MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 50534-115 Tuffside 404
50534-9 Decoral 2787
50534-8 Bravo 560
50534-188 Bravo 720

FROM: William S. Woodrow USW 5-24-90
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

TO: Lewis Stone (PM 21)
Pennsville Herbicide Branch
Registration Division (H7505C)

APPLICANT: Fermenta ASC Corporation
5466 Heisley Road
P.O. Box 8000
Mentor, Ohio 44061-8000

FORMULATION FROM LABEL:

Active Ingredient(s):
Chlorothalonil (tetachloroisophtalalinitrile)
-115
-9
-8
-188
% by wt.
40.4 54.4

Inert Ingredient(s): . . . . . . . . . . . . . . . . . . . . . . . . . .
566 45.6

Total 100.0%
BACKGROUND

The Fermenta ASC Corp. requested precautionary labeling changes and/or the addition of label use claims for the following chlorothalonil products; whose Confidential Statements of formula are similar enough to utilize a single set of supporting acute toxicity data:

**EPA 50534-115 Tuffcide 460**
- chlorothalonil: 40.4%
- Inerts: 59.6%

**50534-9 Dacoril 2787**
- chlorothalonil: 40.4%
- Inerts: 59.6%

**50534-8 Bravo 500**
- chlorothalonil: 40.4%
- Inerts: 59.6%

**50534-188 Bravo 720**
- Chlorothalonil: 46.0%
RECOMMENDATIONS

1) Precautionary labeling change requests:
   a. Request to delete "May be a potential skin sensitizer", under Precautionary Statements for:
      50534-115 Tuffside 404 j
      60634-9 Daconil 2787 j
      50534-18 Bravo 500 j and j
      50534-188 Bravo 720

RSB/PRS recommendation: This request is not justified. The only dermal sensitization study representing the above four products (conducted using Bravo 720; MR10#405460-02), showed that Bravo 720 was a weak contact sensitizer.

b. Fermenta Corp. is justified in removing all statements from the following labels referring to "chlorothalonil ... or this product may produce temporary allergic side effects ..." or "Note to physicians: Person's having an allergic reaction respond to treatment with
antihistamines
50534-115 Tuffside 404
50534-9 Deconil 2287
50534-8 Bravo 500
50534-188 Bravo 720

c. Fermenta Corp. requests adding the following to the 50534-115 labels:
50534-9
50534-8, and:
50534-188

"Note to Physician: Persons having temporary irritation symptoms may respond to treatment with antihistamines or steroid creams and/or systemic steroids is acceptable to RSB/PRS. Note to PBY:
The Fermenta Note to Physician is acceptable provided "may" is inserted into the phraseology suggested by Fermenta.
The "Note to User: This product may produce mild bronchial irritation and temporary irritation of the skin characterized by redness or rash on exposed skin areas. Affected persons
should call a physician,” proposed by Fermenta is also acceptable to RSB/PRAs for the following product labels:

50534-115;
50534-9;
50534-8; and;
50534-188

2) The Fermenta Corp. requests permission to add “prevents fungal growth on caulkks, non-food grade sealants and adhesives” to the 50534-115 Tuffside 404 product label.

The Fermenta Corp. request to add caulkks, non-food grade sealants and adhesives to the 50534-115 Tuffside 404 label is not acceptable to RSB/PRAs as a current acute toxicity profile for 50534-115, as well as for the products listed below follows:

50534-115;
50534-9;
50534-8; and;
50534-188

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A current acute toxicity profile for the products listed above consists of:

**Acute oral study (Bravo 500; 50534-8, 40.4 % A.T.)**

# 87306, 10-19-77

**Tox. Category II Core Guidelines**

**Acute dermal study (Bravo 500; 50534-8, 40.4 % A.T.)**

# 87307, 10-24-77

**Tox. Category IV Core Guidelines**

**Acute dermal study (Bravo-720; 50534-128, 54.07 % A.T.)**

# 158404, 2-7-86

**Tox. Category III Core Guidelines**

**Acute inhalation study (Bravo-500; 50534-8, 40.4 % A.T.)**

# 87310, 12-6-77

**Tox. Category - not determined Supplementary**

*Particle size/size distribution: No MMAD/GSD Accuracy of cloud concentration questionable; respirable particle fraction was an inaccurate, crude estimation.**
EYE IRRITATION STUDY (Bravo-500; 505-24-8, 40.47% A.I.)
# 87177 4-17-81
Tox. Category II Core Guidelines

EYE IRRITATION STUDY (Bravo-500; 505-34-8, 40.47% A.I.)
# 87177 4-17-81
Tox. Category III Core Guidelines

EYE IRRITATION STUDY (Bravo-500; 505-24-8, 40.47% A.I.) # 87178
Tox. Category III Core Guidelines

EYE IRRITATION STUDY (Bravo 720; 505-24-185, 54.47% A.I.) # W11-11006
Tox. Category II Core Guidelines

SKIN IRRITATION STUDY (Bravo 500; 505-24-8, 40.47% A.I. # 4503-77, 87308
Tox. Category IV Core Guidelines

DERMAL SENSITIZATION STUDY (Bravo 720; 505-24-185, 54.07% A.I. # 405460-02-
A weak contact sensitizer.
Core Guidelines
LABELING: 50534-115, 50534-9, 50534-8, 50534-188.

1) The WARNING signal word is appropriate.
2) 50534-115 Tuffslide 404

Precautionary Statements

a. Do not remove the "May be a potential skin sensitizer" statement.

Under First Aid:
Add, "If Swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person."

3) 50534-9 Dacron 7787

Precautionary Statements

a. Do not remove the "May be a potential skin sensitizer" statement.

b. Add "Harmful if swallowed or absorbed through skin, and causes eye injury."

Under First Aid:
Add, "If Swallowed: Call a physician or..."
Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If on skin: Wash with plenty of soap and water. Get medical attention.

If in eyes: Flush with plenty of water. Call a physician.

4) 50534-8 Bravo 500

Precautionary Statements

a. Do not remove the "May be a potential skin sensitizer" statement.

b. Add: "Harmful if swallowed, absorbed through skin, and causes eye injury."

Under First Aid:

Add: If swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce
vomiting or give anything by mouth to an unconscious person.

If on skin: Wash with plenty of soap and water. Get medical attention.

5) 50x34 - 188 Bravo 720
Precautionary Statements
a. Do not remove the "May be a potential skin sensitizer" statement.
b. Add "Harmful if swallowed, absorbed through skin, and causes eye injury."

Under First Aid:
Add "If Swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person."

If on skin: Wash with plenty of soap and water. Get medical attention.
6) Deletion of statements regarding temporary allergic side effects, and Note to Physician as indicated on sample labels, provided by the registrant is acceptable to RSB/PDS. The deletion of "Note to User" under Directions for Use, (50534-115, 50534-9) is acceptable.

7) The addition of a "Note to Physician", as indicated on sample labels, is acceptable provided the word "may" is inserted between the words "symptom and respond".

8) The addition of "Note to User", as shown on the sample label, is acceptable.

9) The label additions shown under 7) and 8) above concern products:

50534-115: Tuffcide 464
50534-9: Deconil 2787
50534-8, and Bravo 500
50634-118: Bravo 770

ADDITIONAL RECOMMENDATION

3) The Registrant must submit an acceptable acute inhalation toxicity study using one of the following Fermonta products: 50534-115 (Tuffcide 464), or 50534-9 (Deconil 2787), or 50534-8 (Bravo 500).
DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1)

Product Manager: (21)
MRID No.: 87306
Testing Facility: Bio/Dynamics
Author(s): W.E. Reagan
Species: Rat: Wistar
Age: Not Stated
Weight: 210-250g
Source: Maryland Farms, Md.
Test Material: Compound 8641-125 (12440500): Liquid
Quality Assurance (40 CFR §160.12):

Conclusion:
1. LD50 (mg/kg): Males = ; Females =
2. The estimated LD50 is 4.29/100 (2.9-6.4) 7/10795% CI.
3. Tox. Category: II
classification: guide A/B 

Procedure (Deviation from §81-1): 5mL50 rats were dosed oral
intubation (5ml/10g/kg) at 5 different dose levels - 7 rat
administered 2.5, 5, 10, 20% solution in water. Animals housed for
Mortality and Toxic symptoms 2-4 hrs post treatment and
at daily intervals for 14 days. Postmortem necropsy on all animals
Reported Mortality

<table>
<thead>
<tr>
<th>DOSAGE (g/kg)</th>
<th>(NUMBER KILLED/NUMBER TESTED)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Males</td>
</tr>
<tr>
<td>2.0 g/kg</td>
<td>3/5</td>
</tr>
<tr>
<td>2.8 g/kg</td>
<td>1/5</td>
</tr>
<tr>
<td>4.0 g/kg</td>
<td>1/5</td>
</tr>
<tr>
<td>5.6 g/kg</td>
<td>1/5</td>
</tr>
<tr>
<td>8.0 g/kg</td>
<td>3/5</td>
</tr>
</tbody>
</table>

Symptomology & Gross Necropsy Findings:

Clinical: Terminal body weight, reduced losses for all animals.
Prominent in females. Dull coat, piloerection, weight loss,
appearance, fecal staining.

Necropsy: Prominent, soft stools, mucus in rectal discharge, red
yellow stool, ten blood, matted hair, matted knees, visceral
fetal tissues of abdomen.
<table>
<thead>
<tr>
<th>DOSE (2.0 mg/kg)</th>
<th>Males</th>
<th>Females</th>
<th>Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>20/1 kg</td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
</tr>
</tbody>
</table>

**Summary:**

1. LD₅₀ (mg/kg): Males = 0.3 Combined = 0.3

**Product Manager:**

**Report No:** 467-67

**Date:** 5-1-69

**Data Review for Acute Dermal Toxicity Testing (181-2)**
DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§610.2)

Product Manager: (21)  
Reviewers:  
RID No.: 158494  
Report Date: 5-11-92  
Author(s): N.H. Wilson  
Species: Rabbit, N 2, white (60% 70% F)  
Sex: Blind compound 7:194-1 Wc.: Not stated  
Test Material: D51-99-1 (Tech. chlorine dioxide) Brabo 720 & 54%  
Quality Assurance (40 CFR §160.12): Adequate  
A 1

Summary:

1. LD50 (mg/kg): Males =  
   Combined =  
   Females =  

2. The estimated LD50 is > 2000 mg/kg  

3. Tox. Category: III. Classification: Guideline

Procedure (deviations from §610.2): 2000 mg/kg applied undiluted and occluded on clipped, shaved 4 cm. x 4 cm. of back, maintained in contact for 24 hours. Animals were observed for trip signs and for mortality frequency during day 1 post test, 7 days test  

Results:

Applicator sites scored for irritation on days 1, 3, and 10 top, 2nd and 3rd day 0, 3, 7, 114  

Reported Mortality

<table>
<thead>
<tr>
<th>DOSAGE (mg/kg)</th>
<th>(NUMBER KILLED/NUMBER TESTED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000 mg/kg</td>
<td>Males</td>
</tr>
<tr>
<td></td>
<td>0%</td>
</tr>
</tbody>
</table>

Macroscopic & Gross Necropsy Findings:

Necropsy performed on all animals.  
Clinical: Local dermal irritation only, low incidence of lesions for most animals. All animals showed body weight gain during study.  
Necropsy: Prominent gross findings included dermal and subcutaneous firm lump (possibly pulmonary infection). No confirmatory related findings.
DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING ($81-3)

Product Manager: (21) Reviewer: W. Woodrow
MRID No.: 87310 Report Date: 5-11-90
Testing Laboratory: Bio/Dynamics Report No. 77-1946
Author(s): W.E. Reinhardt
Species: Rat, Sprague Dawley
Sex: 5/14-5F Weight: 217-300g
Source: Charles River
Test Material: Compound 86441-125 (Group 525), liquid
Quality Assurance (40 CFR §160.12):

Summary:
1. LC50 (mg/kg): Males = ; Females =
   Combined =
2. The estimated LC50 is 2.072 mg/L
3. Mean Concentration:
4. Tox. Category: __ Classification: Supplementary (see 2nd page)

Procedure (deviations from $81-2): Test mat. placed in 3-week 20-do.
fitted with a 2-skin sealed hood. Dose airflow 92.4 L/min.
passed through quartz. Airflow 245 L/gas exposure chamber.
4-hour airflow. Nominal concentration determined. Int. mater.
A separate 1-wk air thru chamber. Animals admitted for

<table>
<thead>
<tr>
<th>Exposure Concentration (mg/L)</th>
<th>(NUMBER KILLED/NUMBER TESTED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.072 mg/L</td>
<td>Males Females Combined</td>
</tr>
<tr>
<td></td>
<td>0% 0% 0%</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Symptomology & Gross Necropsy Findings:
- Mortality and toxicity during exposure & daily testing. Body
  weights recorded at 0, 1, 7, 14, 21 days. Gross necropsy performed
  on all animals.
- During exposure, chamber atmosphere sampled hourly by a
  GCA 300 ppm SL test monitor (Model RDM 20).

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equipped w. a cyclone precollector, which is 100% effective in removing 380 particles or 50% efficient in removing 3.5 μm particles, or 7. Sample tapped in and without precollector to determine 10 μm particles or even (3.5 to 10 μm).

Results: Nominal Concentration = 0.16 mg/l.
Total Mass Concentration (mg/l) (without Cyclone Precollector) = 1.075 (av. of 4 measurements).

No visible dust, alginal cysts. No "definive" types seen during body specimen period. Necropsy findings suggested possibility of some pulmonary trich.

No petrite in 2 day histologic survey. No mm, m, G.S. deviation.
Accuracy of total mass/mg cloud concentration exceed once satisfactory.
Respirable particles (mg) vary only reflect, attention with no verification of accuracy.

Supplementary Data: see above remarks.
DATA REVIEW FOR ACUTE EYE IRRIGATION TESTING (§61-4)

Product Manager: (21) Reviewer: M. W. Custer
ID No.: 87177 Report Date: 5/28/76
Testing Laboratory: Bio/Dynamics, Inc. Report No. 64-5890-00-54
Author(s): N. H. Wilson
Species: Monkeys (Pattens, Cynomolgus) Source: Primate Imports, Post-Hatch, L.F., N.J.
Sex: 4 males Weight: 0.08955
Age: 0.1-4.5
Test Material: 1-11-5 (Brago 500) Liquid
Safety Assurance (40 CFR §160.12): adequate

Summary:
Tox. Category: III Classification: Guidelines

Procedure (Deviations From §61-4): 0.25 ml test material instilled into each eye of 9 monkeys, 1 eye per monkey, to the conjunctival sac. 20 sec. after treatment, eyes of 3 monkeys washed for 1 minute with 10 ml saline; treated eye examined and scored at 2, 4, 6, 8, 10, and 14, 17, 21 days for irritation.

<table>
<thead>
<tr>
<th>Observation</th>
<th>Days</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>7</th>
<th>14</th>
<th>21</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conjunctivae</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
</tr>
<tr>
<td>Edema</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
</tr>
<tr>
<td>Discharge</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
<td>0/9</td>
</tr>
</tbody>
</table>

Trends: Cornea opacity thickened day 14, abated by day 21. No iris involvement. Conjunctival irritation abated by day 14.
DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: (21)
ID No.: 87718
Laboratory: Bio/Physicare, Inc.-

Author(s): D.R. Neandera

Species: Rabbit, N.Z. White
Source: Maryland Breeding Farms - N.C.

Sex: Male
Weight: 0.60 kg

Material: Compound 8641-125 (Bravo 500 - 40-4 to A.I.)

Assurance (40 CFR §160.12): None

Summary:
Tox. Category: III
Classification: Guidelines

Procedure (Deviation from §87.2): 0.1ml test material into one eye

12h following, Eyes: unmedicated. Eyes examined and scored for irritation on days 1, 2, 3, and 7, according to the Denize system.

Results:

<table>
<thead>
<tr>
<th>Observations</th>
<th>Days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Cornea</td>
<td>7/6</td>
</tr>
<tr>
<td>Opacity</td>
<td>0/6</td>
</tr>
<tr>
<td>Iris</td>
<td>6/6</td>
</tr>
<tr>
<td>Conjunctivae</td>
<td>6/6</td>
</tr>
<tr>
<td>Redness</td>
<td>6/6</td>
</tr>
<tr>
<td>Chemosis</td>
<td>6/6</td>
</tr>
<tr>
<td>Discharge</td>
<td>6/6</td>
</tr>
</tbody>
</table>

Remarks: No iris involvement, Corneal involvement absent by day 2. Conjunctival redness absent by day 7. (Present through day 3)

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DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: [211]  
ID No.: [7777]  
Sting Laboratory: Bio/Dynamics  
Distributor: N. H. Wilson  
Species: Rabbit, NZ white  
Sex: M/F  
Weight:  
Source: Dutchland Lab. animals, Denver, PA.  
Sage: 0.1 ml  
Test Material: T-111-3 (Bravo 500)  
 TTC assurance (40 CFR §160.12): adequate  

Summary:

Dox. Category: III  
Classification: Guidelines  
Protocol (Deviation from §81-4): 0.1 ml instilled into each eye 9 times, 20 sec after application (+1 min interval), tested per 3 rabbits, washed for 1 minute, 10 minutes, 60 minutes, 24 hours, 48 hours, 72 hours, 7 days, and 14 days.

<table>
<thead>
<tr>
<th>Observations</th>
<th>(number &quot;positive&quot;/number tested)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hour 1</td>
</tr>
</tbody>
</table>

Results: No iris involvement, Corneal involvement about 6 days. Conjunctival irritation about 10 days.
**DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)**

Product Manager: (21)  
MRID No.: 158493  
Testing Laboratory: WIL Res Labs, Inc.  
Author(s): D. J. Nasr

**Species:** Rabbit, N.Z. White  
**Source:** Michigan Valley Rabbitry, MI  
**Sex:** Male  
**Dosage:** 0.1 mL  
**Test Material:** Bravo 720 (5% O.E. A.I.), liquid  
**Quality Assurance (40 CFR §160.12):** Adequate

**Summary:**

Tox. Category: II  
Classification: Guidelines

Procedure (Deviation From §81-4): 0.1 mL undiluted test material instilled into the conjunctival sac of each rabbit's eye, 20-30 seconds after instilling 0.3 mL of 5% saline, then rinsed with 2.5 cm. of tap water. Eyes examined and scored for irritation according to Draize @ 1, 2, 4, 8, 24 hours, and days 1, 2, 10, 14, and 24 post dosing.

**Observations**

<table>
<thead>
<tr>
<th></th>
<th>Days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>CorneaOpacity</td>
<td>6%</td>
</tr>
<tr>
<td>Iris</td>
<td>0%</td>
</tr>
<tr>
<td>ConjunctivaeRedness</td>
<td>6%</td>
</tr>
<tr>
<td>Chemosis</td>
<td>6%</td>
</tr>
<tr>
<td>Discharge</td>
<td>6%</td>
</tr>
</tbody>
</table>

**Comments:** The scores for the 3 washed (treated) rabbit eyes were considerably less than conjunctival score for unwashed eyes, therefore washed scores were not utilized. Table text continues.
DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5)

Product Manager: [Redacted]
MRID No.: [Redacted]
Testing Laboratory: BioDynamics, Inc.
Author(s): G. H. Hoenan
Species: Rabbit, N 2 white
Sex: Not stated
Weight: 2.15-2.45 kg.
Dosage: [Redacted]
Test Material: Bravo 500 (compound 8641-125) - 46.4% Tech. Chlorothalonil
Quality Assurance (40 CFR §160.12): None

Summary:
The Primary Irritation Index = 1.3
Toxicity Category: IV
Classification: Guidelines

Procedure (40 CFR §160.10): 0.5 ml undiluted test material applied to intact and to abraded test site on clipped back
14 to 16 rabbits, under 5% group. By eye, secured with tape or adhesive wrapped in plastic. Selecting second the
24 hour contact. Animals observed and scored for
Results: Tested at 24 and 72 hours post-application
(mean scores)

24hr intact skin: Erythema: 0.7
            Edema: 0.5

Abraded skin: Erythema: 0.8
            Edema: 0.7

72hrs intact skin: Erythema: 0.8
            Edema: 0.3

Abraded skin: Erythema: 1.2
            Edema: 0.2

\[ \frac{5.7}{4} = 1.4 \] Total 5.2

mild or slight irritation @ 72 hrs. - Tox.

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Category IV
DATA REVIEW FOR SKIN SENSITIZATION TESTING ($81-6)

Product Manager: 21
MRID No.: 405-460-002
Testing Laboratory: Will Bos Lab. Inc.
Author(s): S.K. Shultz, N.H. Wilson
Species: Guinea pig
Sex: 24 M, 24 F
Weight: 376-450 g
Source: Buckser Corp.
Test Material: Bravo 720 (Blind No. 7-154-1) 50.0% w/w
Positive Control Material: Dinitrochlorobenzene (DNCB)
Quality Assurance (40 CFR $160.12): Adequate

Method: Modified Buehler patch-repeated insult

Summary:
1. This product is not a dermal sensitizer.
2. Classification:

Procedure (Deviation From §81-6): An in vivo study was conducted to determine the irritation potential of the test material (Bravo 720) and the control dinitrochlorobenzene (DNCB). Undiluted Bravo 720 was used in 80% ethanol and acetone were used in the main study.

<table>
<thead>
<tr>
<th>Group</th>
<th>Test/Control Material</th>
<th>Number of Animals</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Bravo 720</td>
<td>12 (M, F)</td>
<td>100% 100% 100%</td>
</tr>
<tr>
<td></td>
<td>DNCB (Positive Control)</td>
<td>12 (M, F)</td>
<td>0.1% 0.05% 0.05%</td>
</tr>
<tr>
<td>III</td>
<td>Bravo 720 (Irritation Control-Challenge)</td>
<td>12 (M, F)</td>
<td>-- 100% --</td>
</tr>
<tr>
<td></td>
<td>DNCB (Irritation Control-Challenge)</td>
<td>--</td>
<td>-- 0.05% --</td>
</tr>
<tr>
<td>IV</td>
<td>Bravo 720 (Irritation Control-Rechallenge)</td>
<td>12 (M, F)</td>
<td>-- -- 100%</td>
</tr>
<tr>
<td></td>
<td>DNCB (Irritation Control-Rechallenge)</td>
<td>--</td>
<td>-- 0.05% --</td>
</tr>
</tbody>
</table>

a Bravo 720 was administered in undiluted form during the induction, challenge and rechallenge phases of the study. DNCB was administered in 80% ethanol for the induction phase and in acetone for the challenge and rechallenge phases of the study.

b This irritation control group was treated only at challenge. The same twelve animals served as irritation controls for the test and positive control materials.
Radiation: 0.2 applications per week, 9 total to clipped
back of animals. Dewel volume was 0.4 ml. Dewelvations
were done at the same site. To bone appear.

Animals were sent for 2448 hours after the initial
application, and 21 hours after subsequent applications.

4 days after last application application animals
Challenges at a previously unused (naive) into naive
(control) animal challenged at separate sites with
test and positive control materials—after 2448
hours after application. Each animal in test
and positive control groups were challenged at naive sites.

Results:

1) Positive control: DNBC did not induce specific
reaction.

2) Bravo 720. In order to calculate response
for each challenge, the challenge individual
results at 24 hours + results were considered 0.5:

| Challenge | 24 hrs | 24 hrs
|-----------|--------|--------
| Brav 720 Mean | 0.66   | control 0.38 |
| Rechallenge Mean | 0.54   | control 0.7  |

Conclusion:

Bravo 720 is a weak irritant agent.