



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

NOV 28 1989

007627

11-28-89

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: 61966-R,E,G. Champon. Review of Request For Waiver on Requirement for Either Tolerance or Exemption From Tolerance.

Tox. Chem. Nos. 158, 027
Project No. 0-0153

TO: William Miller, PM #16
Insecticide-Rodenticide Branch
Registration Division (H7505C)

FROM: Pamela M. Hurley Ph.D., Toxicologist *Pamela M. Hurley 11/20/89*
Section I, Toxicology Branch I
Insecticide, Rodenticide Support
Health Effects Division (H7509C)

THRU: Roger Gardner, Acting Section Head
Section I, Toxicology Branch I
Insecticide, Rodenticide Support
Health Effects Division (H7509C)

Roger Gardner
11-20-89

Karl Baetcke Ph.D., Chief
Toxicology Branch I
Insecticide, Rodenticide Support
Health Effects Division (H7505C)

Karl Baetcke
11/20/89

Record No(s). 252414-16

Background and Request:

Champon Pet Products Inc. has submitted three applications for registration of products containing food grade materials. The products will be used as an indoor crack and crevice spray, an outdoor spray (including garden use), a carpet freshener and pet guard and as an outdoor animal repellent. The Registration Division has informed the Registrant that uses "in kitchens" and "in gardens" would require either tolerances or exemptions from tolerances (see memorandum from Anne Lindsay to Penelope Fenner-Crisp, dated November 9, 1989). In response to the comments from the Registration Division, the Registrant stated that "since all the ingredients of the pesticides are GRAS for food use according to FDA regulations and are similar to the substances mentioned in section 180.2(a), it seems reasonable to conclude that they should also be GRAS as pesticides for food applications. We therefore request, in accordance with section 180.2(b) of EPA's regulations, that the Registration Division consider our

1 B

pesticide products as GRAS or as not poisonous or deleterious, thus allowing their use on food products or on food areas without promulgation of a tolerance or exemption therefrom" (see letter from Hogan and Hartson to Herbert Harrison, dated September 25, 1989, page 7). The Toxicology Branch has been requested to review the available data on these products and determine from a toxicological standpoint whether or not tolerances or exemptions from tolerances be required for the intended uses.

Toxicology Branch Response:

The Toxicology Branch (TB-1) has reviewed the available acute toxicity data on the products and has verified that all of the ingredients in the products to be registered are on the FDA Generally Recognized As Safe (GRAS) list. TB-1 is aware that placement on the FDA GRAS list is not 100% assurance that a particular chemical is completely safe from a human health standpoint. However, since acute toxicity testing on one of these products (active ingredients identical in all three) indicates low toxicity (generally toxicity category IV), and since these ingredients have been used in a variety of food products for many years without any indication of deleterious health effects, TB believes that it is not likely that these products will pose a significant threat to human health. Therefore, TB has no objection to allowing an exemption from a tolerance for these products. On the basis of the acute toxicity data, the following toxicity studies are waived for the specific uses requested in the Registration applications (indoor crack and crevice spray, outdoor spray (including garden use), carpet freshener and pet guard and outdoor animal repellent):

- o Subchronic feeding studies in two species
- o Reproduction study
- o Teratology studies in two species
- o Chronic feeding studies in two species
- o Oncogenicity studies in two species
- o Mutagenicity studies (gene mutation, chromosomal aberration, other genotoxic effects)
- o Metabolism data

Specific details on the acute toxicity data for these products are summarized in the memorandum from V. Seabaugh to W. Miller, dated 6/9/89.

AA A

61966-E

(14.2 SQ. INCH LABEL)

007627

NEW
CHAMPON

THE ONLY
100% NATURAL

PRODUCT NAME

CARPET
FRESHENER & PET GUARD

NO
SYNTHETIC
CHEMICALS

JUST SPRINKLE
AND
VACUUM

PLEASANT REAL LEMON
SCENT

GUARANTEED TO WORK

ACTIVE INGREDIENTS: MUSTARD OIL,216%

CAPSICUM OLEORESIN,625%

INERT INGREDIENTS: VEGETABLE OIL, EXTRACT OF LEMON, 99.159%

(8pt. type) → KEEP OUT OF REACH OF CHILDREN

CAUTION: SEE BACK LABEL FOR ADDITIONAL PRECAUTIONARY
STATEMENTS

NET WT. 12 OZ.

(12pt. type)

007627

C.F. BACK LABEL

This carpet freshener is one of our 100% natural products. All ingredients of this product have been listed by the Food and Drug Administration as generally recognized as safe for food use. This triple action formula will eliminate household odors and leave the whole room smelling clean and lemon fresh. It also safely keeps pets away from carpets and upholstered furniture where applied.

Great for pet, smoke and cooking odors.
 Easy to use shaker top.
 Effectively controls pets.
 Great training aid for pets.
 Deodorizes approximately ten 9 X 12 carpets.

Directions For Use

It is in violation of federal law to use this product in a manner inconsistent with its labeling.

1. Sprinkle Champon's Carpet Freshener over desired area.
2. Let product remain on area for ten minutes.
3. Vacuum area thoroughly.

Provides immediate repellent action and regular use when vacuuming will maintain desired control.

Precautionary Statement
 Hazards to Humans and Animals

CAUTION: Avoid contact with skin or eyes. May cause burning sensation to skin, eyes or nose due to capsicum oleoresin.

Statement of Practical Treatment

If on skin, wash with soap and water. If in eyes, flush with plenty of water. If swallowed, burning sensation will occur, mostly in throat. Drink plenty of water. If burning persists, call your physician. Do not sprinkle directly on humans or animals.

ENVIRONMENTAL AND CHEMICAL HAZARDS:

NONE.

STORAGE AND DISPOSAL:

Store in an area inaccessible to children. Wrap empty container prior to disposal. For outdoor pet and animal control, use our 100% Natural Animal Repellent.

CHAMPON
 PET PRODUCTS INC.
 Boca Raton, FL 33487

EPA Reg. No. _____
 EPA Est. No. _____

NEW

619056276

CHAMPON

THE ONLY 100%
NATURAL

OUTDOOR ANIMAL REPELLENT

NO
SYNTHETIC
CHEMICALS

KEEPS DOGS
AND OTHER ANIMALS AWAY FROM
GARBAGE, ~~GARDENS~~ AND LAWNS
READY TO USE
GUARANTEED TO WORK

ACTIVE INGREDIENT: MUSTARD OIL,216%
CAPSICUM OLEORESIN,625%
INERT INGREDIENTS: VEGETABLE OIL, EXTRACT OF LEMON, 99.159%

(6pt. type) → KEEP OUT OF REACH OF CHILDREN

CAUTION: SEE BACK LABEL FOR ADDITIONAL PRECAUTIONARY
STATEMENTS

↑
(10 pt. type)

NET WT. 8 OZ.

A.R. BACK LABEL

This animal repellent is one of our 100% natural products. All ingredients in this product have been listed by Food and Drug Administration regulation as generally recognized as safe for food use. This dual-action formula will repel animals with an acute sense of smell and/or taste. The lemon scent is pleasant for humans and the unique formula is guaranteed to work or your money will be refunded. Effective against dogs, cats, raccoons, squirrels, deer and rabbits.

Directions For Use

It is in violation of federal law to use this product in a manner inconsistent with its labeling.

- Garbage Bags: Spray entire bag thoroughly, including bottom.
- Vegetable Garden: Spread stream around perimeter of garden. Use directly on fruits or vegetables where necessary. If sprayed on fruits or vegetables, wash thoroughly before eating. (May be used through harvest.)
- Lawns: Spray in areas where repellent is needed. (Do not saturate.)
- Landscape Areas: Spread even stream along flower beds on flowers or shrubs as needed.
- Bird Feeders: Spray feeder, poles, treebranch as needed.

Reapply as necessary.

Precautionary Statement
Hazards to Humans and Animals

CAUTION: Avoid contact with skin or eyes. May cause burning sensation to skin, eyes or nose due to capsaicin oleoresin.

Statement of Practical Treatment

If on skin, wash with soap and water. If in eyes, flush with plenty of water. If swallowed, burning sensation will occur, mostly in throat. Drink plenty of water. If burning persists, call your physician. Do not spray directly on humans or animals.

ENVIRONMENTAL AND CHEMICAL HAZARDS:
NONE.

STORAGE AND DISPOSAL:
Store in an area inaccessible to children. Wrap empty container prior to disposal.

Use Restrictions

For outdoor use only. (Will stain fabric.) Do not use where vegetable crops would be undesirable, such as car finishes, home siding or screens. May stain concrete, spray inconspicuous area to test.

For indoor repellent, try our 100% Natural Carpet Freshener with Pet Guard

CHAMPON
PET PRODUCTS INC.
Boca Raton, FL 33487

EPA Reg. No. _____
EPA Est. No. _____

7/11 A

61966-R

007627

(9 SQ. INCH LABEL)

NEW
CHAMPON

THE ONLY
100% NATURAL

INSECT CONTROL

NO
SYNTHETIC
CHEMICALS

READY TO USE
GUARANTEED TO WORK

ACTIVE INGREDIENTS: MUSTARD OIL,216%
CAPSICUM OLEORESIN,625%
INERT INGREDIENTS: WATER, EXTRACT OF LEMON, 99.159%

FOR OUTDOOR/INDOOR USE

(6 pt. type) → KEEP OUT OF REACH OF CHILDREN

CAUTION: SEE BACK LABEL FOR ADDITIONAL PROCAUTIONARY
STATEMENTS

↑
(10 pt. type)

NET WT. 8 OZ.

I.C. BACK LABEL

This insect control is one of our 100% natural products. All ingredients in this product have been listed by Food and Drug Administration regulation as generally recognized as safe for food use. This dual-action formula kills on contact and it also maintains a repellent action against many garden and household insects. Convenient ready-to-use formula.

Directions For Use

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

INDOORS

COCKROACHES, WATERBUGS, SILVERFISH, CRICKETS, EARWIGS, CENTIPEDES, MILIPEDES: Spray until wet in cracks, around baseboards, behind and beneath cabinets, refrigerators, sinks, stoves, around plumbing, and other localized areas infested with insects. Repeat as necessary.

ANTS: Spray until surface is wet, applying to ant trails, around doors and window frames and wherever ants enter the house. Repeat as necessary.

SPIDERS: Spray pests directly wherever possible. Apply to localized areas where infestations occur. Spray until surfaces are wet, particularly around windows, doors, baseboards and crawl spaces. Repeat as necessary.

OUTDOORS

ANTS: Thoroughly wet hill and runways. Repeat applications as infestations warrant and as reinfestations occur. Spray around walkways, porch, patios and foundations to prevent insect infestation.

For Garden Use: Spray light mist on plants to prevent harmful insect damage. May be used up to day of harvest. Wash all fruits and vegetables thoroughly before eating.

Precautionary Statement
Hazards to Humans and Animals

CAUTION: Avoid contact with skin or eyes. May cause burning sensation to skin, eyes or nose due to capsiicum oleoresin

Statement of Practical Treatment

If on skin, wash with soap and water. If in eyes, flush with plenty of water. If swallowed, burning sensation will occur, mostly in throat. Drink plenty of water. If burning persists, call your physician. Do not spray directly on humans or animals.

ENVIRONMENTAL AND CHEMICAL HAZARDS:
NONE.

STORAGE AND DISPOSAL:
Store in an area inaccessible to children. Wrgp empty container prior to disposal.

Use Restrictions

Do not use on fabric or carpet as stains will result.

CHAMPON
PET PRODUCTS INC.
Boca Raton, FL 33487



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

61966-R

007627

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM (CONFIDENTIAL FORMULA INFORMATION INCLUDED)

Subject: EPA Registration Number Champon's Insect Control
(EPA 61966-R). Champon's Animal Repellent and Carpet
Freshner (EPA 61966-E). Champon's Animal Repellent
(EPA 61966-G). Action Code 161. Accession Numbers:
410441-01, 410440-02, 410801-01).

From: Van M. Seabaugh *JMS 6-9-84*
Precautionary Review Section *E 6/9/84*
Registration Support Branch
Registration Division (H7505C)

To: William H. Miller (PM 16)
Insecticide - Rodenticide Br.
Registration Division (H7505C)

Applicant: Champon Pet Products Co., Inc.
3019 Cormorant Road
Delray Beach, Florida 33444

Summary:

The product tested was Champon's All Natural Animal Re-
pellent (EPA 61966-G). The differences in the formulations
are given (Table 1; confidential information). EPA 61966-E
differs from the identical formulas of EPA 61966-R and EPA
61966-G. The 6 acute toxicity tests must be conducted for
EPA 61966-E. The summary reviews for the acute toxicity
tests are given (Table 2).

Page 10 is not included in this copy.

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
 - The product confidential statement of formula.
 - Information about a pending registration action.
 - FIFRA registration data.
 - The document is a duplicate of page(s) _____.
 - The document is not responsive to the request.
-

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Table 2: Summary Of Acute Toxicity Tests Evaluated By EPA

Testing Laboratory: Toxicology Monitor Labs., Inc. Report No.	Acute Toxicity Test	EPA Class- ification	Toxicity Category/comments
88-506	§81-2; dermal toxicity	supplementary	No toxicity category was assigned. Only a limit test of 2 g/kg (0/10 mortality) was conducted. A 5 g/kg test is needed to assign the toxicity category.
88-500	§81-3; inhalation	supplementary	No toxicity category was assigned. Another study must be conducted, or information submitted indicating that at least 25% of the particles are respirable, aerodynamic diameter is 1 um or less.
88-506	§81-4; eye irritation	guideline	Toxicity Category IV. "Positive" discharge scores indicated at the 1 hr. reading (6/6). No other "positive" scores were indicated thru day 3 readings.
88-506	§81-6; skin sensitization	supplementary	The study must be conducted again. The lab must submit information indicating a positive control. Twenty animals per group must be used for the test and vehicle control. The lab must indicate why page 5 of MRID #410801-01 stated guinea pig sensitization, but the animal numbers stated rabbit numbers 1-10. Are individual numbers kept for all animals in the lab?

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Table 2: (Acute Toxicity Tests Con't.)

Testing Laboratory: Toxicology Monitor Labs., Inc. Report No.	Acute Toxicity Test	EPA Class- ification	Toxicity Category/comments
88-5/6	§81-5; skin irritation	guideline	IV. Primary Irritation Index = 0.46.
88-506	§81-1; oral toxicity	minimum	IV. Estimated LD50 >5 g/kg.

Labeling

We object to the use of the word "natural", and this must be removed. Other comments include the following:

1. The word "natural" is not an EPA approved term. We consider this statement directly or indirectly implying that the pesticide is recommended or endorsed by any Agency of the Federal government. (40 CFR §162.10)
2. "It is not harmful to any animal, but will repel animals from desired areas." There are no data to support the first part of this statement, and must be deleted or modified.
3. None of the confidential statement of formulas match the label ingredient statements.
4. We cannot comment any further on the labeling until we receive satisfactory data for the acute studies as outlined in the EPA individual reviews for the submitted data.

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CHAMPON'S
 ALL NATURAL
**CARPET
 FRESHENER**
 ANIMAL REPELLENT

With Real Lemon Scent!

Keeps dogs, cats and other pets away
 from desired areas, rooms and furniture

GUARANTEED TO WORK

KEEP OUT OF REACH OF CHILDREN

CHAMPON PET PRODUCTS INC.
 Boca Raton, FL 33487

NET WT. 12 OZ.

CHAMPON'S ALL NATURAL CARPET FRESHENER AND ANIMAL REPELLENT IS AN APPROVED PRODUCT OF THE NATIONAL PET CARE ASSOCIATION. IT IS A SAFE AND EFFECTIVE SOLUTION FOR PET OWNERS. DIRECTIONS FOR USE: CAUTION: DO NOT SPRINK ON CARPETS, FURNITURE, OR OTHER DESIRED AREAS. ACTIVE INGREDIENTS: 2.5% LEMON OIL. INERT INGREDIENTS: 97.5% WATER. THE PRODUCT IS NOT TO BE USED ON CARPETS, FURNITURE, OR OTHER DESIRED AREAS. IT IS A SAFE AND EFFECTIVE SOLUTION FOR PET OWNERS. CAUTION: DO NOT SPRINK ON CARPETS, FURNITURE, OR OTHER DESIRED AREAS. STORAGE: STORE IN A COOL, DRY PLACE. DISPOSAL: DISPOSE OF IN ACCORDANCE WITH LOCAL REGULATIONS. CAUTION: DO NOT SPRINK ON CARPETS, FURNITURE, OR OTHER DESIRED AREAS. THE PACKAGE IS NOT TO BE REUSED.

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DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1)

Product Manager: (16).
Reviewer: Van M. Seabaugh
NRID NO.: 410440-02
Testing Facility: Tex monitor Lab., Inc., 33 W. Chicago, Illinois
Author(s): Study director Michael Kukalinski
Report Date: *
Species: Sprague Dawley rats
Sex: male and female
Age: _____
Weight: 200-300 g.
Source: not stated
Observation Days (Post Exposure): (14) other ()

EPA Reg. No. 6446-26
 Champion's All Natural
 Animal Repellent

Test Material: amber colored liquid; Champion's All Natural
Quality Assurance (40 CFR §160.12): Animal Repellent.
 Statement signed by quality assurance officer and study director.

Conclusions:

- LD50 (mg/kg): Males (M) = _____; Females (F) = _____; Combined (C) = _____
- The estimated LD50 is greater than 5g/kg.
- Toxicity Category: IV. Classification: core - minimal

Procedure (Deviations From §81-1): The test was conducted in accordance with EPA 502.5

Results:

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Reported Mortality

Dosage (5/kg)	Mortality Ratio (number killed/number tested)		
	Males (M)	Females (F)	Combined (C)
	0/5	0/5	0/10

Comments:

* Michael Kukalinski said to me in a telephone conversation that the starting date was January 17, and the animals were necropsied on 1-31-89.

DATA REVIEW FOR
ACUTE DERMAL TOXICITY TESTING (§81-2)

007627

Product Manager (PM): 16
 Reviewer: Van M. Seabaugh 6-25-84
 MRID No.: 410441-01 Report Date: 1-31-84
 Testing Laboratory: Tox Monitor Labs, Inc., 33 W. Chicago Ave.
 Author(s): not stated Michael Kalmicki Oak Park, Ill.
 Species: New Zealand Albino Rabbits
 Sex: m Wt.: 2.05 Source: not given
 Dosage: 2 g/kg 2.55 Test Material: Amber
colored liquid

Quality Assurance (40 CFR §160.12): Statement signed by
Quality Assurance Unit and study director of Tox Monitor Labs Inc.
However, the applicant needs to sign it also.
 Summary:

LD50: _____
 Toxicity Category: _____
 Classification: core - Supplementary +

Procedure (Deviations From §81-2): See Report No. 88-516
 * see comment below

Results:

1. Reported Mortality:

Dosage (g/kg)	Mortality Ratio (number killed/number tested)		
	Males (M)	Females (F)	Combined (C)
	0/5	0/5	0/10

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2. Comments:

* only a limit test for 2 g/kg was conducted. Additional testing must be conducted (i.e. 5 g/kg; also see 1984 revised FIFRA Guidelines for additional information) to establish if the product is in toxicity category III or IV.

Toxicity Category III Toxicity Category IV

DATA REVIEW FOR
ACUTE INHALATION TOXICITY TESTING (§81-2)

007627

EPA Reg. No. 61966-06

Product Manager (PM): 16
 Reviewer: Van M. Seabaugh DMK 5-25-84
 MRID No.: 410441-01 Report Date: 2-16-84
 Testing Laboratory: Tox Monitor Lab. Inc. 33 W. Chicago Ave.
 Author(s): Michael Kukulinski, B.S. (Stud) OAK PARK, Illinois
 Species: Sprague-Dawley rats We.: 200-300 grams
 Sex: male and female (5 each) Source: Bio-Lab Corp., St. Paul, Minnesota
 Dosage: _____ Test Material: Champion's
All Natural Animal Repellent

Quality Assurance (40 CFR §160.12): The Applicant needs to sign the GLP statement.

Summary: C
 LD50: _____
 Toxicity Category: _____
 Classification: core - Supplementary

Procedure (Notations and/or Deviations From §81-2): Tox Monitor report w. TM 88-500
Male and female rats (5 each) were exposed for 4 hours in a dynamic inhalation chamber to the test material (5 mg/L target level; 4.21 mg/L gravimetric concentration). There was a 14-day observation period.

Results:

1. Reported Mortality:

Dosage (mg/L)	Mortality Ratio (number killed/number tested)		
	Males (M)	Females (F)	Combined (C)
5 mg/L targeted (4.21 mg/L gravimetric concentration)	0/5	0/5	0/10

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No significant changes were reported for observations.

2. Comments:

The particle size distribution of the test material was reported to be tested at 120 minutes using a mervel Cascade Impactor.

* If the mass median diameter (aerodynamic) reported in a study is larger than 1µm, we can accept the study if at least 25% of the particles are 1µm or less. The data submitted did not indicate this. 16 condition was met. Therefore, the test must be

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

0415 EPA Reg. No. 6146-06 E

Product Manager (PM): 16
 Reviewer: Van M. Seabaugh 5-26-84
 MRID No.: 410441-01 Report Date: Summary sheet dated 1-30-84
 Testing Laboratory: Tox monitor LABS INC., 33 W. Chicago Ave. Oak Park, Ill.
 Author(s): Not stated. Michael Kukulinski (study director)
 Species: New Zealand Albino Rabbits
 Sex: males . Wt. young adult . Source: not specified
 Dosage: 0.1 ml . Test Material: Amber Colored liquid; Champion's All Natural Animal Repellent

Quality Assurance (40 CFR §160.12): Statement signed by study director and quality assurance person

Summary:

Toxicity Category: IV

Classification score: Guidelines

Procedure (Deviation From §81-4): TM 88-506

Results:

	Observations (number "positive"/number tested).							
	Hour	Days						
	1	1	2	3	4	7	14	21
Cornea	0/6	0/6	0/6	0/6	-	-	-	-
Iris	0/6	0/6	0/6	0/6	-	-	-	-
Conjunctivae	0/6	0/6	0/6	0/6	-	-	-	-
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	-	-	-	-

Comments:

The reported results stated a maximum mean score of 4.3 out of a possible 110 scoring system, and a toxicity category III. EPA does not use the "110" system.

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DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5)

Product Manager (PM): 16
 Reviewer: Van N. Seabaugh DMC 5-31-84
 MRID No.: 410440-02 Report Date: 4
 Testing Laboratory: Tox Monitor Labs, Inc. 33 W. Chicago Ave. Oak Park, Ill.
 Author(s): Study director: Michael Kukulinski
 Species: New Zealand Albino Rabbits
 Sex: males Source: not specified
 Wt.: young adult
 Dosage: 0.5ml Test Material: Champion's all Natural Animal Rep. diet; amber colored liquid
 Quality Assurance (40 CFR §160.12): Statement signed by Study director and quality assurance unit
 Summary: The Primary Irritation Index = 0.46
 Toxicity Category: IV
 Classification: core - guideline
 Procedure (Deviations From §81-5): Tox Monitor Laboratories
 Report No.: Tm 88-506

Results:

P.I.I = 0.46

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Special Comments:

on 5-30-84
 Animals numbered 1-6. I asked Kukulinski how they numbered their animals, and he said numerically. Each year they start with zero.* Also he said that the starting/ending dates are January 17 and 31 (necropsy).

* However, the reports just are numbered with rabbits one thru six.

DATA REVIEW FOR
SKIN SENSITIZATION TESTING (§81-6)

007627

Product Manager (PM): 16
Reviewer: Van M. Seabaugh DMS 5-24-84
MRID No.: 410801-01 Report Date: 4-14-84
Testing Laboratory: Tox Monitor Labs. Inc., 33 W. Chicago, Oak Park, Illinois 60302
Author(s): Study Director - Michael Kakulinski; William Thomson (Technician)
Species: Dunkin Hartley albino guinea pigs
Sex: Young adult males Source: not specified
Wt.: _____
Dosages: _____ Test Material: Champion's All Natural Animal Repellent. Amber Colored Liquid.

Quality Assurance (40 CFR §160.12): Statement by Robert F. Locke (Quality Assurance Unit); Michael Kakulinski

Method: modified Draize procedure. Draize, J.H. 1955, Dermal Test, Food Drug Cosmet, Vol 5, 10, 722-732. Draize, J.H. 1964, Summary of the Safety of Chemicals in Food, Drug, and Cosmetic

Summary: Review of the Safety of Chemicals in Food, Drug, and Cosmetic

~~Classification Code: _____~~

Procedure (Deviation From §81-6): TAX MONITOR LABORATORIES
REPORT NO: TM 88-506

Sample Preparation: Prepared and dosed as a 2% suspension.

Results: Only ten test animals were used. An initial dose level of 0.05 was made followed by injections of 0.1 ml three times weekly on alternate days for three weeks (10 injections). The challenge dosage was not specified.

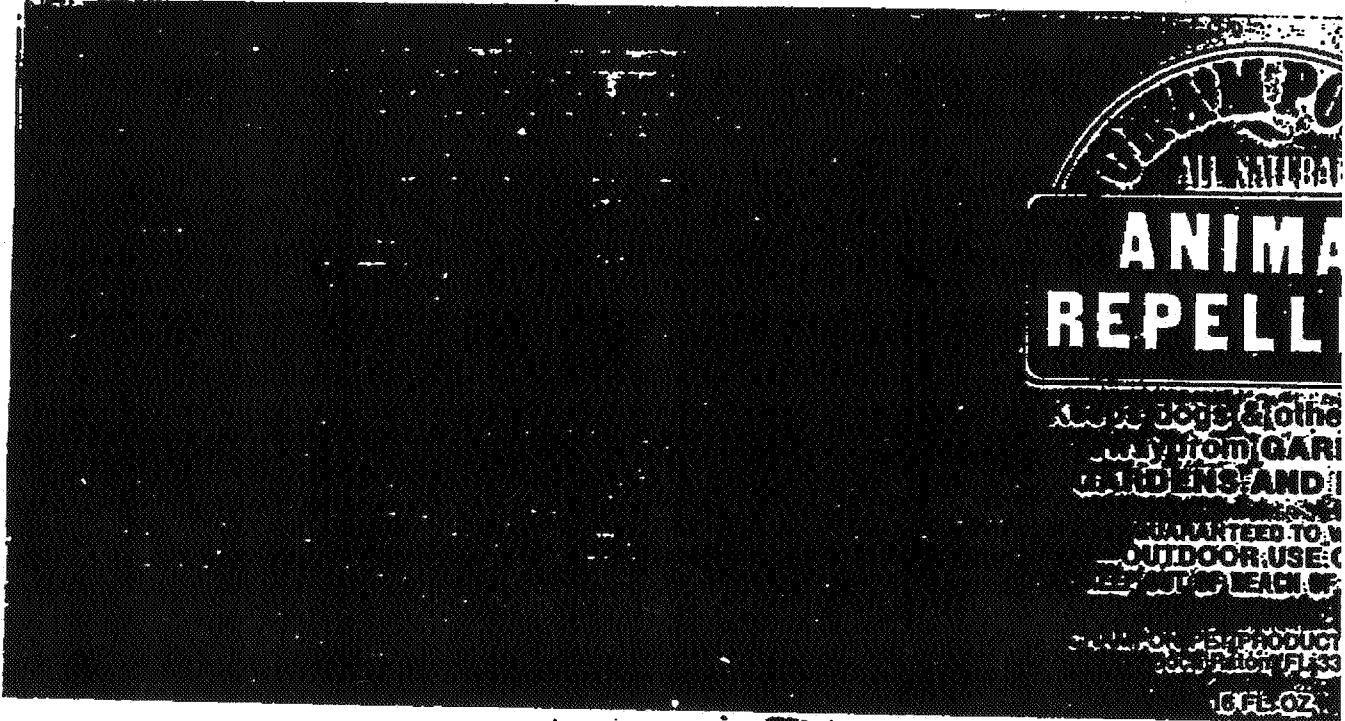
The study should be conducted again taking into consideration the following information. The laboratory should submit information for a positive control. Twenty animals per group should be used for the test and vehicle control. The test substance is 0.05 or 0.1 ml of a 0.1% solution, suspension, or emulsion. The vehicle is usually physiological saline, paraffin oil, or propylene glycol. The challenge dose is 0.05 ml of a 1.0% solution or suspension.

The dermal irritation test for this product indicated a primary irritation index of 0.46 (toxicity category IV)

Page 5 of MRID # 410801-01 stated guinea pig sensitization but the animal numbers stated rabbit numbers 1-10.

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007627

Champion Insect Control is an all natural control, using all FDA food ingredients. It is not harmful to any animal or human but will kill and control insects from Chaired to flea. Effective against ants, fleas, ticks, mites, cockroaches, crickets, chiggers and other types of insects.

DIRECTIONS FOR USE: LAWN AND GARDENS: Spray generously in shaded areas of lawns, vegetable or fruit, wash thoroughly with a mild soap and water solution before eating. **INDOOR USE:** Only use in kitchen or other food, non-toxic areas. If applied on food, wash with water. Can also be sprayed under dishes and in cabinets, under sinks, or behind the refrigerator.

ACTIVE INGREDIENTS: Extract of marigold 2100, extract of chives 6000.

INERT INGREDIENTS: Vegetable oil, extract of lemon.

STATEMENT OF PURPOSE: This product is not harmful to humans but may cause some irritation to skin and eyes due to contact of chives.

IF ON SKIN: Wash with soap and water.

IF IN EYES: Flush with plenty of water.

IF SWALLOWED: Do not induce vomiting unless directed by a doctor. Drink plenty of water. If having trouble, call physician.

STORAGE: Store in an area inaccessible to children.

DISPOSAL: Wrap empty container and put in trash.

CAUTION: DO NOT SPRAY DIRECTLY ON ANIMALS OR HUMANS.
Pat. Pending No. 833,817



KILLS
ants, fire ants, n
grasshoppers an
GRASS
FOR USE IN
LIMITED INDOOR
CHAMPION PE
EACH

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12

Page 22 is not included in this copy.

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

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Stedman's Medical Dictionary 22nd Ed. (1972)

Dextrin

British gum; one of a group of α -1,4-glucoses (dextrins) formed during the enzymic hydrolysis of starch; amylopectin, or glycogen. On

hydrolysis by α -amylase, converted to glucose and maltose (usually white dextrin)

The polysaccharide fragment remaining at the end (limit) of exhaustive hydrolysis of amylopectin or glycogen by α -1,4-glucan maltohydrolase, which hydrolyze the α -1,6 bonds at branch points.

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d. transglycosylase (EC 2.4.1.25), D enzyme; disproportionating enzyme; a 1-4-glycosyltransferase converting maltodextrin into amylose and glucose by transferring parts of 1,4-glucan chains to new 4 positions

Condensed Chemical Dictionary (1971)

p. 539

malto (3-hydroxy-2-methyl-4-pyrone)
 $\text{CH}_3\text{C}_5\text{H}_7\text{O}$ (a) (lit). white crystalline
 powder having a characteristic caramel-
 butterscotch odor, and suggestive of a
 fenyl - strawberry aroma in dilute solution.

Slightly soluble in water, insoluble in
 alcohol and diethyl ether. mp 110°C.

Found in malted barley. Nontoxic.

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The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
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