12345

45735-2

15

FIFRA
CONFIDENTIAL BUSINESS INFORMATION
DOES NOT CONTAIN NATIONAL
SECURITY INFORMATION (E.O. 12356)

MEMORANDUM

Date: February 13, 1984

Subject: EPA File Symbol 45735-E (2)
RO-PEL

From: Deloris F. Graham
FHB/TSS

To: William Miller
Product Manager (16)

Applicant: Burlington Scientific Corporation
100 Fairchild Avenue
Plainview, NY 11803

Active Ingredient:
Benzyldiethyl [(2,6 xylyl carbamoyl)
methyl] ammonium saccharide..... 0.06%
Inert Ingredients.....99.93%

Background: No data submitted, only one other product registered with same active ingredient, but inert ingredients differ.

Recommendation:

1. The appropriate acute data (Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation, Primary Dermal Irritation and Dermal Sensitization) must be submitted before necessary precautionary labeling can be determined.

Date: February 13, 1984

Subject: EPA File Symbol : 45735-E
RO-PEL

From: Delores J Graham
PMB/SRB E 2/13/84

To: William Miller
Product Manager (16)

Applicant: Burlington Scientific Corporation
100 Fairchild Avenue
Plainview, New York 11803

Active Ingredient:
Benzyldiethyl [(2,6-xylyl carbamoyl)
methyl] ammonium saccharide 0.065%
Inert Ingredients 99.935%

Background: No data submitted. Only one other product registered with same active ingredient, but inert ingredients differ.

Recommendation
(1) The appropriate acute data (Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation, Primary Dermal Irritation and Dermal Sensitization) must be submitted before necessary precautionary labeling can be determined.

"RO-PEL"

HIGHLY EFFECTIVE RODENT AND ANIMAL REPELLENT

Non-toxic to plant and animal life. — out
Ecologically safe control or rodent, - out
pest and predator damage. Also stops
domestic animals from chewing, licking
or gnawing.

INGREDIENTS:

[redacted]

{(2,6 xylyl carbamoyl) methyl}
ammonium saccharide .065%

Net 1 qt.

Needs detailed use directions

DIRECTIONS FOR USE:

← type?

Spray (or paint) on bark of trees, siding, fences, posts, telephone poles, furniture, garbage bags.

Cover entire area to be protected.

Do not dilute! Do not mix with other chemicals!

The repellent contains special penetrating ingredients which will permeate the bark of trees or outer layer, remain intact, and withstand outside elements. Annual re-application is advised. Before using on painted surfaces, first test small area to determine whether RO-PEL's ingredients will damage the paint. Do the same with plastics or fabrics. If in doubt, please test first!

PRECAUTIONS

Avoid contract with eyes,skin, food or clothing.
If repellent gets on eyes, skin or clothing, wash thoroughly with plenty of water. Get medical attention if irritation persists.
Avoid tasting! The taste is extremely bitter and very unpleasant.

CAUTION: KEEP OUT OF REACH OF CHILDREN!

Never use on food, edible plants or directly on the fruit or nuts of trees. Do not use on sugar maple trees, since the RO-PEL could affect the taste of the maple syrup.

Store RO-PEL in cool area away from heat.
Wash hands thoroughly after use and dispose of unneeded material and empty containers.

RO-PEL can also be used to control damage caused by dogs, cats, beavers, raccoons, rats, opossum, wolves, deers, gophers, coyotes, squirrels, crows, woodpeckers and other varmints and prowlers.

E.P.A. ESTABLISHMENT #45735-NY
E.P.A. REGISTRATION #

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT

DO NOT KEY NEXT PAGE

Date: February 13, 1984

Subject: EPA File Symbol: 45735-E
RO-PEL

From: Delores J Graham
EHE/SRB E 2/13/84

To: William Miller
Product Manager (16)

Applicant: Burlington Scientific Corporation
100 Fairchild Avenue
Plainview, New York 11803

Active Ingredient:
Benzyldiethyl [(2,6 xylyl carbamoyl) methyl] ammonium saccharide 0.0
Inert Ingredients 99.9

Background: No data submitted, Only one other product registered with same active ingredient, but inert ingredients differ.

Recommendation
(1) The appropriate acute data (Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation, Primary Dermal Irritation and Dermal Sensitization) must be submitted before necessary precautionary labeling can be determined.

4

"RO-PEL"

HIGHLY EFFECTIVE RODENT AND ANIMAL REPELLENT

Non-toxic to plant and animal life. — out
Ecologically safe control or rodent, — out
pest and predator damage. Also stops domestic animals from chewing, licking or gnawing.

INGREDIENTS:

[redacted]

{(2,6 xylyl carbamoyl) methyl}
ammonium saccharide .065%

Net 1 qt.

needs detailed use directions

DIRECTIONS FOR USE:

← type?

Spray (or paint) on bark of trees, siding, fences, posts, telephone poles, furniture, garbage bags.

Cover entire area to be protected.

Do not dilute! Do not mix with other chemicals!

The repellent contains special penetrating ingredients which will permeate the bark of trees or outer layer, remain intact, and withstand outside elements. Annual re-application is advised. Before using on painted surfaces, first test small area to determine whether RO-PEL's ingredients will damage the paint. Do the same with plastics or fabrics. If in doubt, please test first!

PRECAUTIONS

Avoid contract with eyes,skin, food or clothing.
If repellent gets on eyes, skin or clothing, wash thoroughly with plenty of water. Get medical attention if irritation persists.
Avoid tasting! The taste is extremely bitter and very unpleasant.

CAUTION: KEEP OUT OF REACH OF CHILDREN!

Never use on food, edible plants or directly on the fruit or nuts of trees. Do not use on sugar maple trees, since the RO-PEL could affect the taste of the maple syrup.

Store RO-PEL in cool area away from heat.
Wash hands thoroughly after use and dispose of unneeded material and empty containers.

RO-PEL can also be used to control damage caused by dogs, cats, beavers, raccoons, rats, opossum, wolves, deers, gophers, coyotes, squirrels, crows, woodpeckers and other varmints and prowlers.

E.P.A. ESTABLISHMENT #45735-NY
E.P.A. REGISTRATION #

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT

5

IRB/TSS Precautionary Labeling Review July 20, 1984

TO: PM-16

SUBJECT: 45735-E
RO-PEL
Burlington Scientific Corporation
100 Fairchild Avenue
Plainview, New York 11803.

In TSS: 05-03-84
Record No.: 120179
Action: 161

FORMULATION: Liquid

Active Ingredients:
Benzyldiethyl [2,6 Xylylcarbamoyl) Methyl]
Ammonium Saccharide..... 0.065%

Inert Ingredients..... 99.935%
Include [redacted]

BACKGROUND: This is an application for a new registration. Applicant has submitted toxicology data to support registration. Product is proposed to be used as a repellant.

COMMENTS: According to the studies submitted by registrant, ROPEL seems to be a fairly non-toxic substance, and will be placed in toxicity category IV for acute oral, acute dermal, primary skin and primary eye irritation exposures. However, all studies lack the actual raw data. Clarification is needed on the following points, before IRB/TSS can review and validate the data:

A. When and where were the studies done?

B. Who conducted the tests?

C. Was there a quality control step built into the testing procedure.

D. Details of test protocols used, like strain, age, weight of animals; clinical signs of toxicity, recovery time, necropsy findings etc.

E. For acute oral and acute dermal LD_{50} studies, tests should be done on both male and female of the species and observations should be recorded for 14 days.

6

National Laboratory Audit Program does not have Burlington Scientific Corporation on its records, nor could they find it in Lab Directory prepared by Texas Research Institute. Thus we have no way of knowing whether this laboratory follows the GLP or not, and it is all the more important for us to have full details of the protocols used before we can validate the studies.

We would also like to see a copy of the actual proposed label for precautionary labeling review.

Note to PM: We suggest that Bill Jacobs should consider the possibility of declaring [redacted] an active ingredient in ~~it's~~ this formulation (see attached note by Phil Hutton). Bill added a comment to his review of 6/21/84.

Rita Kumar
IRB/TSS Rita Kumar

EPA File Symbol 45735-E(2) 2-13-18 FINAL CISP-4

Page X is not included in this copy.

Pages ____ through ____ are not included.

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.

---

16 hrs.

IRB/TSS Precautionary Labeling Review 6-12-85

TO: PM-16

SUBJECT: 45735-E
RO-PEL
Burlington Biomedical and Scientific Corp.
100 Fairchild Ave.
Plainview, NY 11803.

In TSS: 2-21-85
Record #:
Accession #: 256593

Formulation: Liquid ready to use.
Active Ingredient:
Bitrex - - - - - - - - - - 0.065%
Inert Ingredients - - - - - - 99.935%
(Include [redacted] and 0.035% thymol).

Background: Registrant has provided details of the acute toxicity studies pursuant to TSS review of July 20, 1984 and Agency's letter of Aug. 3, 1984. Product is proposed to be used outdoors as a coarse spray or paint to repel deer, beaver, ~~rats,~~ mice, squirrels, dogs and cats.

→

Submitted Data: Studies were done at
Microphysic
51 Ave. de L'observatoire
Paris, France.

1. Acute Oral LD50: 5M mice of an unspecified strain were given oral doses of 19.6, 39.2, 58.8 g/kg, with 7 days observation. There were no mortalities; toxic signs were ataxia and convulsions, clearing in 30-60 minutes. Study classification: Core Supplementary data. See comment 1.

2. Accumulated Skin Irritancy Test: 6F Hartley albino rabbits received 5 applications a week for 5 successive weeks, of 0.1 ml of undiluted material. No irritation was recorded. There is a descrepancy between the description of this study, and test method. Test animals are described as 6 female albino rabbits in study summary whereas in test method application is claimed to be made to 10 guinea pigs. Study classification: Invalid study because of the above mentioned inconsistency. The purpose of this study is not clear anyway, as it is not required in EPA guidelines.

(10)

→

3. Primary Skin Irritation: 6F albino rabbits received 4 hour occluded dermal exposure to 0.5 ml to each of the 2 abraded and 2 unabraded skin patches. Observations were made for 2 days. No irritation was recorded.
PDIS = 0.
Study classification: Core minimum data.
Product classification: Toxicity category IV.

4. Phototoxicity: 6F Hartley albino rabbits received 4 hour dermal exposure to 0.1 ml on each of the two skin patches per rabbit. One patch per rabbit was then irradiated for 15 minutes with lamps of 280-400 nm intensity. Observations were made at 24 and 48 hours after irradiation and no irritation was reported. Purpose of this study is unclear; but if phototoxicity testing was a requirement, this study would be acceptable and product would be classified as non-phototoxic.

5. Dermal Sensitization: Maximization test with Takase method. 15F Hartley guinea pigs were given 2 induction applications, first as ~~an~~ a subcutaneous injection of 0.2 ml and second as a 48 hours occluded topical application of 0.5 ml, given a

(1)

applied topically
week later. Challenge was given 2 weeks later, with 0.1 ml for 24 hours. No irritation was reported after challenge. ~~See~~ Irritation scores after induction applications were not recorded.
Study classification: Core supplementary data.
See Comment 2.

Registrant was to submit copies of literature on oral toxicity of bitrex and [redacted]

6. Acute Dermal LD_{50}: LD_{50} values were cited for ingredients of RoPel. ~~But~~ those values when extrapolated to the percentage in this product will be as follows:

Bitrex — 2061 g/kg

[redacted]

Thymol — 5714 g/kg.

Looking at these acute dermal toxicity values, subject product will be placed in toxicity category IV for acute dermal exposure.

7. Primary Eye Irritation: 6 F albino rabbits received 0.1 ml in one eye of each rabbit. Eyes were washed after 5 minutes. Mild conjunctival irritation was noted in 3 treated eyes, clearing within 1 hour.
Study classification: Core minimum data.
Product classification: Toxicity category IV.

8. Acute Inhalation: A waiver for this test has been requested.
See comment 3.

Comments:

1. According to guidelines, this study should be considered supplementary data because testing was done only on male mice. However, IRB/TSS has decided to accept it as core minimum for this registration ~~only~~ because this product is fairly nontoxic and even if there was a tenfold increase in susceptibility of female mice, product would be in toxicity category IV.

2. According to guidelines, this study should be considered supplementary data because irritation scores of induction applications were not reported. IRB/TSS has decided to accept it as core minimum because product has a PDIS value of 0 and induction scores would be hard to get. Besides, challenge did not show any irritation so regardless of what the induction scores would be, product would be considered a non-sensitizer.

(15)

3. In view of the fact that product is meant for outdoor use only and label clearly states that application should be made with a coarse sprayer, acute inhalation LC_{50} study is not required at this time.

4. Based on given data, product has been placed in the following toxicity categories:-

Exposure Route	Toxicity Category
Acute oral LD_{50}	IV
Acute dermal LD_{50}	IV
Primary Eye Irritation	IV
Primary Dermal Irritation	IV
Dermal Sensitization	Non-sensitizer
Acute Inhalation	Not needed.

5. The following ~~statement~~ should be added to precautionary statements: "Avoid breathing spray." Bitrex might be irritating to respiratory tract.

6. Note to Steve: Please check label format.

7. Just for record: According to Mal Hallander this product is registered in Canada and has been placed on their GRAS list because of extremely

low acute toxicities.

Rita Kumar
IRB/TSS