UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1 AUG 1995

Cheryl R. Montgomery, Ph.D.

C.R. Montgomery & Associates

P.O. Box 1243

East Arlington, MA 02174-0021

Dear Dr. Montgomery:

Subject: Revised Labeling and Confidential Statements of Formula

Skedaddle! Insect Protection for Children

EPA Registration Number 64583-2

Submissions Dated June 1, 1995, and July 14, 1995

The labeling referred to allove, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, subject to the comments listed below:

- 1. The term "new" for this product must be eliminated. The Agency does not allow a reference to "new" on a product after one year of registration.
- 2. Add the statement "Wash treated clothing." to the Directions for Use section.
- 3. Provide a clarification regarding the removal of the Contraindications Statement.

The confidential statement of formula for the basic formulation (dated July 12, 1995) is not acceptable. The total weight of each component in the formulation sums to greater than 100 pounds, although the total weight box states otherwise.

The confidential statement of formula for the alternate formulation (dated May 19, 1995) is not acceptable for the reasons given below:

- 1. The total weight of each component in the formulation sums to greater than 100 pounds, although the total weight box states otherwise.
- The nominal concentrations of the active ingredient and its isomers as reflected on the confidential statement of formula do not match the active ingredient statement on the accepted

Tabel.			 CONCURRENC	ES	····		
SYMBOL P	mic.						
GIRNAME N . /	ww			****************		************	
DATE M	31/45		***********		*************		

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

US GPO 1994 522 503/82085 9 4.

3. The alternate formulation does not meet the criteria described at 40 CFR 152.43. Specifically, the alternate formulation does have the same certified limits for the active ingredient and its isomers as the basic formulation.

The Agency does acknowledge, however, that upon correction of the above-stated deficiencies, this formulation will be designated as the alternate formulation. This correction was also noted in the Agency's letter dated December 23, 1994.

If you have any questions or comments, please contact me at (703) 305-6788.

Sincerely,

RPK

Richard P. Keigwin, Jr. Product Manager 10 Insecticide-Rodenticide Branch Registration Division (7505C)

3.14

ACCEPTED
With COMMENTS
in EPA Letter Dated

1 AUG 1995

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pessicide registered under EPA Rcg. No.

Reporte Fine

| Continue | Contin

Protection from Ticks, Mosquitoes, and Biting Files

ACTIVE INGREDIENTS:

N.N-Dietry)-n-toluemide . 6.2%

Related Controunds 0.3%

MERT INGREDIENTS ... 93.5%

OTAL:....100.0%

CAUTION

Keep Out of Reach of Children See back panel for additional

precautionary statements.

4 FL. OZ. (118 ml.)

BEST COPY AVAILABLE

skedaddle!

insect Protection for Children

A new, revolutionary kind of insect protection. Our "controlled release" technology provides 2-hour repellency with only 6.5% of the active repelling ingredient. You've got to try it to believe it!

INDICATIONS: For protection from mosquitoes, ticks (including ticks that may carry Lyme Disease), biting flies, chiggers, fleas, gnats and no-see-ums. A single application provides effective repellency for two hours.

DIRECTIONS FOR USE: It is a violation of federal law to use this product in a manner inconsistent with its labeling. Read all directions before using this product. Adults should instruct and closely supervise children in the proper use of this product. Do not use on infants without first consulting a physician. Use just enough product to cover exposed skin areas. Apply to hand for application to face and neck and rub on. Avoid overexposure. Frequent reapplication and saturation is unnecessary for effectiveness.

After returning indoors, wash treated skin with soap and water.

PRECAUTIONARY STATEMENTS: Hazards to Humans. CAUTION: For external use only. Causes moderate but temporary eye injury. Avoid contact with eyes. Do not apply to eyes or mouth and do not apply to the hands of young children. Do not use under clothing. Do not apply over cuts, wounds, or irritated skin. Use of this product may cause skin reactions in rare cases. If you suspect that you or your child is reacting to this product, wash treated skin and call your local poison control center. If you go to a doctor take this product with you. If in eyes: Flush with plenty of water. If irritation persists get medical attention.

STORAGE: Store away from heat in an area inaccessible to children.

DISPOSAL: Do not reuse empty container. Immerse empty container in water, rinse thoroughly three times, and offer to your local recycling program or wrap in paper and discard in trash.

Questions? Comments? Write To: LittlePointCorp., PO Box 410295, Cambridge, MA, 02141 or Call: 1-800-243-2929, EMail:LittleP.am.com

US Patent No. 5,221,535 US Patent No. 5,188,837 Other Patents Applied For ©1995 LittlePoint Corp. EPA Reg. No. 64583-2 EPA Est. 50678-NJ-1



4

100 -

1 AUG 1995

Cheryl R. Montgomery, Ph.D. C.R. Montgomery & Associates P.O. Box 1243 East Arlington, MA 02174-0021

Dear Dr. Montgomery:

Subject: Revised Labeling and Confidential Statements of Formula

Skedaddle! Insect Protection for Children

EPA Registration Number 64583-2

Submissions Dated June 1, 1995, and July 14, 1995

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, subject to the comments listed below:

- 1. The term "new" for this product must be eliminated. The Agency does not allow a reference to "new" on a product after one year of registration.
- 2. Add the statement "Wash treated clothing." to the Directions for Use section.
- 3. Provide a clarification regarding the removal of the Contraindications Statement.

The confidential statement of formula for the basic formulation (dated July 12, 1995) is not acceptable. The total weight of each component in the formulation sums to greater than 100 pounds, although the total weight box states otherwise.

The confidential statement of formula for the alternate formulation (dated May 19, 1995) is not acceptable for the reasons given below:

- 1. The total weight of each component in the formulation sums to greater than 100 pounds, although the total weight box states otherwise.
- The nominal concentrations of the active ingredient and its isomers as reflected on the confidential statement of formula do not match the active ingredient statement on the accepted

label.				CONCURRENC	es				
SYMBOL	Pmio								
SURNAME	Yerrom.					***********			
DATE	7 3145								

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

3. The alternate formulation does not meet the criteria described at 40 CFR 152.43. Specifically, the alternate formulation does have the same certified limits for the active ingredient and its isomers as the basic formulation.

The Agency does acknowledge, however, that upon correction of the above-stated deficiencies, this formulation will be designated as the alternate formulation. This correction was also noted in the Agency's letter dated December 23, 1994.

If you have any questions or comments, please contact me at (703) 305-6788.

Sincerely,

RPK

Richard P. Keigwin, Jr. Product Manager 10 Insecticide-Rodenticide Branch Registration Division (7505C)

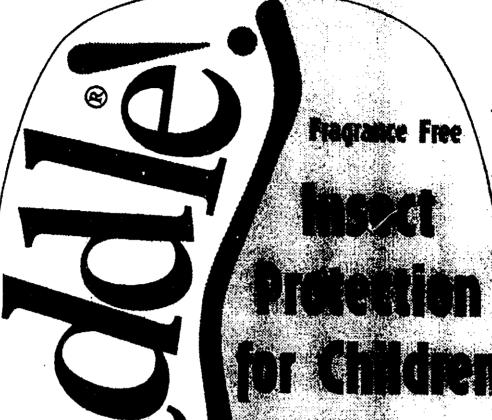
ACCEPTED

with COMMENTS
In EPA Letter Dated

1 AUG 1995

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesucide registered under EPA Reg. No.

64583-2



Protection from Ticks, Mosquitoes, and Biting Files

ACTIVE INGREDIENTS:

N.N-Diethyl-ri-toluamide .. 6.2% Related Compounds ... 0.3% NERT INGREDIENTS ... 93.5%

CAUTION

Keep Out of Reach of Children See back panel for additional precautionary statements.

4 FL. OZ. (138 ml.)

BEST COPY AVAILABLE

skedaddle!

insect Protection for Children

A new, revolutionary kind of insect protection. Our "controlled release" technology provides 2-hour repellency with only 6.5% of the active repelling ingredient. You've got to try it to believe it!

INDICATIONS: For protection from mosquitoes, ticks (including ticks that may carry Lyme Disease), biting flies, chiggers, fleas, gnats and no-see-ums. A single application provides effective repellency for two hours.

DIRECTIONS FOR USE: It is a violation of federal law to use this product in a manner inconsistent with its labeling. Read all directions before using this product. Adults should instruct and closely supervise children in the proper use of this product. Do not use on infants without first consulting a physician. Use just enough product to cover exposed skin areas. Apply to hand for application to face and neck and rub on. Avoid overexposure. Frequent reapplication and saturation is unnecessary for effectiveness. After returning indoors, wash treated skin with soap and water.

PRECAUTIONARY STATEMENTS: Hazards to Humans. CAUTION: For external use only. Causes moderate but temporary eye injury. Avoid contact with eyes. Do not apply to eyes or mouth and do not apply to the hands of young children. Do not use under clothing. Do not apply over cuts, wounds, or irritated skin. Use of this product may cause skin reactions in rare cases. If you suspect that you or your child is reacting to this product, wash treated skin and call your local poison control center. If you go to a doctor take this product with you. If in eyes: Flush with plenty of water. If irritation persists get medical attention.

STORAGE: Store away from heat in an area inaccessible to children.

DISPOSAL: Do not reuse empty container. Immerse empty container in water, rinse thoroughly three times, and offer to your local recycling program or wrap in paper and discard in trash.

Questions? Comments? Write Tu: LittlePointCorp., PO Box 410295, Cambridge, MA, 02141 or Call: 1-800-243-2929. EMail:LittleP.am.com

US Patent No. 5,221,535 US Patent No. 5,188,837 Other Patents Applied For ©1995 LittlePoint Corp. EPA Reg. No. 64583-2 EPA Est. 50678-NJ-1



BEST COPY AVAILABLE