

New York State Department of Environmental Conservation

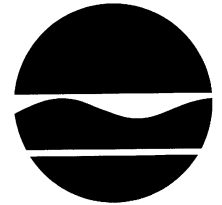
Division of Solid & Hazardous Materials

Bureau of Pesticides Management, 11th Floor
625 Broadway, Albany, New York 12233-7254

Phone: 518-402-8788 **FAX:** 518-402-9024

Website: www.dec.ny.gov

E-Mail: ppr@gw.dec.state.ny.us



Alexander B. Grannis
Commissioner

January 25, 2008

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Rebecca Horton
Agent for Lilly Miller Brands
c/o Registrations by Design, Inc.
118 ½ East Main Street, Suite 1
Salem, Virginia 24153-3805

Mr. Joseph Jankauskas
Cutting Edge Formulations, Inc.
5106 Bristol Industrial Way, Suite 400
Buford, Georgia 30518

Dear Ms. Horton and Mr. Jankauskas:

Re: Registration of Worry Free Brand Weed & Grass Killer (EPA Reg. No. 82052-3-33116) Containing the Active Ingredient d-Limonene. Chemical Code: 079701.

The New York State Department of Environmental Conservation (Department) has completed its technical review of the major change in labeling (MCL) application received on November 19, 2007 which is a substitution for the original application submitted by the basic registrant, Cutting Edge Formulations, Inc., on February 6, 2006. The basic registrant has chosen to market their product through the sub-registrant Lilly Miller Brands, Inc. Therefore, the final product label that will be actively sold into New York State will be the above-referenced product.

D-Limonene is currently registered in New York State for use in insecticides, pet products, and in cleaning products for disinfection. Worry Free Brand Weed & Grass Killer is the first use of d-Limonene as an herbicide in a ready-to-use formulation of 17.5% for control of annual weeds, grasses, and broadleaves on borders, patios, driveways and sidewalks.

The active ingredient and herbicidal use pattern were previously reviewed for the application to register Nature's Avenger Concentrate Weed Controller Herbicide (EPA Reg. No. 82052-1) and Nature's Avenger Weed Controller RTU Herbicide (EPA Reg. No. 82052-3). This application was denied on August 25, 2006 for dermal exposure concerns.

Cutting Edge Formulations, Inc., resubmitted their application to register the Ready-to-Use formulation on August 6, 2007 along with primary skin irritation studies and primary eye irritation studies intending to show that homeowner use of this product without personal protective equipment (PPE) is acceptable given the precautionary text required on the product label. This additional information has been reviewed and has alleviated the Department's concerns for dermal exposure.

The application package for Nature's Avenger Weed Controller RTU Herbicide (EPA Reg. No. 82052-3) and additional information were received on August 6, 2007 and determined to be complete for purposes of technical review on September 5, 2007. Pursuant to the review time frame specified in ECL §33-0704.2, a registration decision date of February 1, 2008 was established. The Department has conducted the following technical review for impacts to human health as a result of potential increased exposure to homeowners from application/use of the product. The following review summary is provided.

Human Health Risk Assessment:

The New York State Department of Health (NYSDOH) reviewed the additional information submitted by Cutting Edge Formulations, Inc., to register the pesticide product Nature's Avenger Weed Controller Ready to Use (RTU) Herbicide (EPA Reg. No. 82052-3) in New York State. Nature's Avenger Weed Controller Ready to Use (RTU) Herbicide is labeled for control of most weeds in non-crop areas.

In our initial review of this product, we noted that the active ingredient d-limonene was not very acutely toxic to laboratory animals by the oral or dermal routes of exposure (no acute inhalation toxicity study data are available). However, d-limonene was both a skin and eye irritant and demonstrated skin sensitizing properties.

Because the Nature's Avenger RTU product is labeled for spot treatments only, and thus exposures should be minimal, we do not expect d-limonene to cause systemic effects. However, at the time of our initial review, we did not have product specific acute toxicity/irritation data and the available data on the active ingredient d-limonene indicated that it can cause eye and skin irritation, as well as skin sensitization. While we noted that the RTU formulation of this pesticide product should mitigate the eye and skin contact that can occur from mixing concentrates, the product label contains the precautionary statement: "May cause eye or skin irritation." Consequently, we recommended that the registrant include a statement on the label requiring that users wear long-sleeved shirt and long pants, gloves and protective eyewear before registration of Nature's Avenger RTU in New York State.

In response to our recommendation requiring personal protective equipment (PPE) on the product label, the registrant submitted primary skin irritation and primary eye irritation studies on the formulated RTU end product for our review. Although the United States Environmental Protection Agency (USEPA) has not reviewed these studies, they were conducted according to the Agency's Health Effects Test Guidelines. In the primary eye irritation study, 0.1 milliliters of the RTU end product was instilled in the right eye of three rabbits. Corneal opacity, slight effects on the iris, and conjunctivitis (characterized by redness, swelling and discharge) were observed in all treated eyes one hour after instillation of the test material. The severity of irritation began to decrease gradually after 24 hours and cleared by Day 7 of the study. In the primary skin

irritation study, 0.5 milliliters of the RTU end product was applied to a six square centimeter area on the skin of three rabbits and covered with a patch for a period of four hours. All three animals exhibited well-defined erythema and slight edema one hour after the patch was removed from the test site. This level of irritation was still present after two days and began to gradually decrease starting on the third day of the study. Although edema was cleared by the end of the study (Day 14), very slight erythema was still present on one rabbit. The laboratory performing these irritation studies classified Nature's Avenger RTU as moderately irritating to the skin and eyes, which appears consistent with the USEPA classification scheme and corresponds to Toxicity Category III.

According to the USEPA Label Review Manual, discretionary use of PPE label statements is recommended to protect human health in circumstances where it is warranted by the product's use pattern and toxicity or irritation potential. However, there are no regulatory requirements for PPE on residential/consumer use products. A search of other homeowner oriented RTU, nonselective herbicides currently registered in New York State revealed products with similar eye and skin irritation potential as Nature's Avenger RTU. These products likewise contain the "Caution" signal word, similar precautionary statements, and no requirements for PPE (such as long-sleeved shirt, long pants, gloves or protective eyewear) on the label.

The newly supplied registrant studies indicate that Nature's Avenger Weed Controller RTU Herbicide is a moderate eye and skin irritant. The existing label statements for the Nature's Avenger RTU product ("Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Harmful if inhaled. Avoid breathing vapor. May cause eye or skin irritation. Wash thoroughly with soap and water after handling.") should provide sufficient advice to users so they can reduce the risk of eye and skin irritation and dermal sensitization. These statements also exceed or are comparable to those of other pesticide products currently registered in New York State with similar use patterns and irritant potential. The fact that this product is a ready-to-use formulation, is packaged in modest-sized containers (24 fluid ounces) and is labeled for spot treatment only, should also serve to minimize the likelihood that users would experience significant eye or skin effects from proper use.

Product Registration Summary:

The Department will accept the substitution of the distributor product labeling provided by Lilly Miller Brands for Worry Free Brand Weed & Grass Killer (EPA Reg. No. 82052-3-33116) in place of Nature's Avenger Weed Controller Ready to Use (RTU) Herbicide (EPA Reg. No. 82052-3) for general use in New York State.

Enclosed for your record, is a copy of the stamped accepted labeling and the Certificate of Registration for Worry Free Brand Weed & Grass Killer (EPA Reg. No. 82052-3-33116). Please note that a proposal by Lilly Miller Brands, Cutting Edge Formulations, Inc., or any other applicant, to register a product that contains d-limonene, and whose labeled uses are likely to increase the potential for significant impact to humans, nontarget organisms, or the environment, would constitute a MCL application. Such an application must be accompanied by a new application fee and meet the requirements listed in Appendix 1.B. of "New York State Pesticide Product Registration Procedures" (September 2005). Such information as well as forms can be accessed at our website as listed in our letterhead.

Ms. Rebecca Horton and Mr. Joseph Jankauskas

4.

Please be aware that any unregistered product may **not** be sold, offered for sale, distributed, or used in New York State.

Please contact our Pesticide Product Registration Section, at (518) 402-8768, if you have any questions.

Sincerely,

Maureen P Serafini

Maureen P. Serafini
Director
Bureau of Pesticides Management

Enclosure

ecc: w/enc. - R. Mungari - NYS Dept. of Ag. & Markets
- A. Grey/E. Horn - NYS Dept. of Health
- W. Smith - Cornell University, PSUR

ACCEPTED
FOR REGISTRATION

JAN 25 2008

NYSDEC

OCT - 5 2007

Fast Acting

WORRYFREE
BRAND

**Weed & Grass
Killer**

for **ORGANIC**
GARDENING

- Can Be Used Around Pets and Wildlife
- Clean Citrus Scent

Ready To Use

Mata malezas y gramas

Kills Annual Weeds, Grasses and Broadleaves
For Use on Borders, Patios, Driveways and Sidewalks

ACTIVE INGREDIENT	17.5%
d-limonene (citrus oil)	82.5%
INERT INGREDIENTS	100.0%
Total	

OMRI
ORGANIC MATERIALS HANDLING INSTITUTION

KEEP OUT OF REACH OF CHILDREN

CAUTION See back panel for additional Precautionary Statements and First Aid

MANTÉNGASE FUERA DEL ALCANCE DE LOS NIÑOS

PRECAUCIÓN Consulte el panel posterior para conocer los riesgos de precaución adicionales y los primeros auxilios

NET CONTENTS/CONTENIDO NETO 1 QT. (32 FL. OZ.) (946 ml)



WORRYFREE
**Weed & Grass
Killer**
for **ORGANIC**
GARDENING

Ready To Use

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Harmful if inhaled. Avoid breathing vapor. May cause eye or skin irritation. Wash thoroughly with soap and water after handling.

FIRST AID

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted con detalle. (If you do not understand the label, find someone to explain it to you in detail.)

If on Skin or Clothing:	<ul style="list-style-type: none"> • 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.
If in Eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lens, if present, after the first 5 minutes. Then continue rinsing eye. • 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.	

See attached booklet for additional Precautionary Statements

Worry Free is a registered trademark of Central Garden & Pet.

Distributed by: LILLY MILLER BRANDS

1340 Treat Blvd, Suite 650

Walnut Creek, CA 94597

EPA Reg. No. 82052-3-33116 EPA Est. No. 82052-GA-1

www.worryfreebrand.com

LM119-01

CLOSE BOOKLET HERE

NOTA: Toda la vegetación con que tenga contacto se verá afectada. Evite el contacto con plantas que desee conservar. Rociar en exceso o a la deriva puede dañar o eliminar la vegetación con que entre en contacto.

ALMACENAMIENTO Y ELIMINACION

Almacenamiento: Almacene en un lugar fresco y seco inaccesible para niños y mascotas.

Eliminación del Pesticida:

Si está vacío: No vuelva a usar este envase. Téilo a la basura o, si está disponible, ofrézcalo para reciclaje.

Si está parcialmente lleno: Llame a su agencia local de desechos sólidos para obtener instrucciones sobre cómo eliminarlo. Nunca elimine el producto no utilizado en ningún drenaje interior o exterior.

Condiciones de venta y garantía

Las Instrucciones de este producto reflejan la opinión de los expertos con base en las pruebas y en el uso en el campo. Se considera que las instrucciones son confiables y que se deben seguir cuidadosamente. Sin embargo, es imposible eliminar todos los riesgos inherentes asociados con el uso de este producto. Los daños a los cultivos, la falta de efectividad u otras consecuencias involuntarias que puedan resultar debido a factores tales como las condiciones climáticas, presencia de otros materiales o el uso del producto de una manera inconsistente con sus etiquetas, todo lo que se encuentra fuera del control del Fabricante, Distribuidor o Vendedor. Hasta donde lo permita la ley que aplica y para ser consistente con la misma, todos estos riesgos los asume el Comprador.

Para obtener más información sobre este producto pesticida (incluso si tiene preguntas sobre salud, emergencias médicas o incidentes con pesticidas), llame al National Pesticide Information Center al 1-800-858-7378. Para todas las demás consultas: info@excelmktg.com.

WORRYFREE
Weed & Grass
Killer

for **ORGANIC**
GARDENING

Ready To Use

SHAKE WELL BEFORE USING

- For use on borders, driveways, patios, sidewalks, around mature trees and ornamentals, around buildings, in residential greenhouses, fencerows and around flower beds
- For outdoor use around the home
- Does not stain brick, concrete, or pavement
- Quick Visible Results

Consulte el folleto interior para obtener la traducción al español



Worry Free is a registered trademark of Central Garden & Pet.

Distributed by:
LILLY MILLER BRANDS
1340 Treat Blvd., Suite 650
Walnut Creek, CA 94597
EPA Reg. No. 82052-3-33116
EPA Est. No. 82052-GA-1
www.worryfreebrand.com

LM119-01

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Harmful if inhaled. Avoid breathing vapor. May cause eye or skin irritation. Wash thoroughly with soap and water after handling.

FIRST AID

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted con detalle. (If you do not understand the label, find someone to explain it to you in detail.)

If on Skin or Clothing:	<ul style="list-style-type: none"> • 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.
If in Eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lens, if present, after the first 5 minutes. Then continue rinsing eye. • 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.

PHYSICAL AND CHEMICAL HAZARDS

Combustible: Do not use or store near heat or open flame.

ENVIRONMENTAL HAZARDS

Do not apply directly to water or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

Este producto es un herbicida de amplio espectro que contiene D-limonene. D-limonene es el aceite cítrico que se extrae de la cáscara de las naranjas. No es selectivo y controla la mayoría de malezas anuales, tanto gramas como de hoja ancha. Para uso en áreas sin cultivos, arriates, caminos de acceso, patios, aceras, alrededor de plantas ornamentales y árboles maduros, alrededor de edificios, en invernaderos residenciales, en la tierra no cultivada al lado de las cercas y alrededor de los lechos de flores.

Este producto actúa velozmente con resultados visibles rápidamente. El contacto foliar da como resultado el control de las gramas y malezas de hoja ancha anuales así como una reducción máxima del crecimiento de las malezas perennes de raíces profundas. Es necesario repetir el tratamiento para el control de las malezas perennes. Rocíelas hasta que estén completamente mojadas. Para obtener un rendimiento óptimo, es necesario cubrir **completamente** las malezas objetivo.

Para el control de MALEZAS ANUALES PEQUEÑAS: Aplique este producto al follaje de las malezas pequeñas (que midan menos de 6 pulgadas) asegurándose de que las hojas estén completamente mojadas y cubiertas de manera uniforme. No lo aplique si hay una fuerte amenaza de lluvia dentro de las siguientes dos horas.

Para control de MALEZAS ANUALES MAS GRANDES y DESTRUCCION COMPLETA de las MALEZAS PERENNES: Las malezas anuales más grandes (que midan más de 6 pulgadas) y las perennes son más difíciles y puede ser necesario volver a aplicar el tratamiento. Haga el tratamiento tal como se describió anteriormente.

Los mejores resultados se obtienen cuando se aplica a malezas jóvenes que están creciendo activamente. Las malezas maduras, inactivas o endurecidas debido al estrés ocasionado por la humedad son más resistentes a los tratamientos de herbicidas.

No aplique este producto por medio de ningún tipo de sistema de irrigación.

PRIMEROS AUXILIOS

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted con detalle.

Si cae en la piel o en la ropa:

- Quite la ropa contaminada.
- Enjuague la piel inmediatamente con mucha agua por 15-20 minutos.
- Llame al centro de control de envenenamiento o al médico para obtener recomendaciones de tratamiento.

Si entra en los ojos:

- Mantenga el ojo abierto y enjuague con agua despacio y con cuidado por 15-20 minutos. Si tuviera lentes de contacto, quítelos después de lavarse con agua los primeros 5 minutos. Luego continúe lavando el ojo.
- Llame al centro de control de envenenamiento o al médico para obtener recomendaciones de tratamiento.

Tenga a la mano el envase del producto o la etiqueta cuando llame al centro de control de envenenamiento o al médico, o al buscar tratamiento.

RIESGOS FISICOS Y QUIMICOS

Combustible: No use ni almacene cerca de calor o de llamas abiertas.

RIESGOS AMBIENTALES

No lo aplique directamente al agua o en áreas entre mareas bajo la marca alta promedio de agua. No contamine el agua al deshacerse de la que usó para limpiar o enjuagar el equipo.

INSTRUCCIONES

Es una violación a la Ley federal usar este producto de forma inconsistente con su etiqueta.

AGITE BIEN ANTES DE USAR

6

DIRECTIONS FOR USE

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

SHAKE WELL BEFORE USING

This product is a broad spectrum weed killer that contains d-limonene. D-limonene is the citrus oil that is extracted from the rind of oranges. It is non-selective and controls most annual weeds, both grasses and broadleaves. For use on non-crop areas, borders, driveways, patios, sidewalks, around mature trees and ornamentals, around buildings, in residential greenhouses, fencerows and around flower beds.

This product is fast acting with quick visible results. Foliar contact results in control of annual grasses and broadleaves and top growth reduction of deep rooted perennial weeds. Re-treatment is required for control of perennial weeds. Spray until thoroughly wet. For best performance, **complete** coverage of target weeds is necessary.

For Control of SMALL ANNUAL WEEDS: apply this product to the foliage of the small weeds (less than 6 inches) making sure leaves are thoroughly wet and uniformly covered. Do not apply if a strong threat of rain is expected within 2 hours.

For Control of LARGER ANNUAL WEEDS and BURNDOWN of PERENNIAL WEEDS: Larger annual weeds (more than 6 inches) and perennials are more difficult and may require re-treatment. Treat as described above.

Best results are obtained when applied to young, actively growing weeds. Weeds that are mature, dormant or hardened due to moisture stress are more resistant to herbicide treatment.

Do not apply this product through any type of irrigation system.

3

NOTE: All contacted vegetation is affected. Avoid contacting desirable plants. Overspray or drift will injure or kill contacted vegetation.

STORAGE AND DISPOSAL

Storage: Store in a cool, dry place inaccessible to children and pets.

Pesticide Disposal:

If empty: Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Conditions of Sale and Warranty

The Directions For Use of this product reflects the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result, because of factors such as weather conditions, presence of other materials, or use of the product in a manner inconsistent with its labeling, all of which are beyond the control of Manufacturer, Distributor or the Seller. To the extent consistent with applicable law, all such risks are assumed by the Buyer.

For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378. All other inquiries: info@excelmktg.com.

4



para **jardinería orgánica**

- Elimina las malezas anuales, gramas y de hoja ancha
- Resultados rápidos
- Se puede usar donde hay mascotas y vida silvestre
- Limpio aroma cítrico

Listo para usar**AGITE BIEN ANTES DE USAR**

- Para uso en arriates, caminos de acceso, patios, aceras, alrededor de plantas ornamentales y árboles maduros, alrededor de edificios, en invernaderos residenciales, en la tierra no cultivada al lado de las cercas y alrededor de los lechos de flores
- Para uso exterior alrededor del hogar
- No mancha el ladrillo, concreto o pavimento
- Resultados visibles rápidamente

AVISOS DE PRECAUCION**RIESGOS PARA HUMANOS Y ANIMALES DOMESTICOS**

PRECAUCION Es dañino si se absorbe a través de la piel. Evite el contacto con ojos, piel o ropa. Dañino si se inhala. Evite respirar el vapor. Puede ocasionar irritación en los ojos o en la piel. Lávese completamente con agua y jabón después de manipularlo.

5