

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505C) 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20004

EPA Reg.

Number:

Date of Issuance:

53883-152

OCT 31 2005

NOTICE OF PESTICIDE:

<u>x</u> Registration \_\_\_\_ Reregistration

(under FIFRA, as amended)

Term of Issuance: Conditional

Cyper Horse Spot- On

Name and Address of Registrant (include ZIP Code):

Control Solutions, Inc. 5903 Genoa- Red Bluff Pasadena, Texas 77507-1041

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

- Submit and/or cite all data required for registration/ reregistration of your product when the Agency requires all registrants of similar products to submit data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
- Make the labeling changes listed below before you release the product for shipment:
  - a. Add the phase "EPA Registration No.53883-152."
- b. Revise the hazard to humans statement to read as follows: "This product may cause hypersensitivity with prolonged use in some individuals.". The other human hazard and first aid statements may be deleted since they received a toxicity category IV rating. The acute inhalation study is waived based on the product being non- volatile and packaged in a very small container. Move the precautionary statements pertaining to horses to the directions for use section on the label.

Signature of Approving Official:	Date:



- c. The data do not support repellent claims up to [3 months][21 days]. The product provided marginal control for eight days against face, house and horse flies. Therefore delete all other pest claims.
- d. Likewise remove all "kills" claims relating to House, Face and Horse flies because the submitted data do not indicate that exposure to horses treated with the formulation resulted in the mortality of flies. Based on the data submitted revise the front panel claims to read as follows: "Repels Face Flies, Horse Flies, House Flies for up to [1 week] [8 days].", "Kills [and] [&] Repels Mosquitoes (culex spp.) for up to 11 days", "Kills [and] [&] Repels [Nuisance] Mosquitoes (culex spp.) for up to 11 days", "Protects Horses from Face Flies, Horse Flies, House Flies for up to [1 week] [8 days].", Protects Horses from Mosquitoes (culex spp.) for up to 11 days", "Protects Horses from [Nuisance] Mosquitoes (culex spp.) for up to 11 days", "One [Dose] [Treatment] Lasts up to [1 week] [8 days]", "Ready To Use", and "Ready To Use- No Dilution Required".

## e. Delete "Protects Horses from Ticks.".

- f. Delete "Waterproof", "Prevents Mosquitoes that Transmit West Nile Virus from Feeding on Horses up to [3 weeks][21 days]]", "Kills Mosquitoes, The Vector of West Nile Virus for up to [3 weeks][21 days]]", "Quick Acting & Long Acting.", "Protects Against Biting Insects 50% Longer than Permethrin Squeeze-On's for Horses", "Protects Against Biting Insects on Horses 50% Longer than Permethrin Squeeze- On Products.", "Works 50% Longer", and "Works 50% Longer than Permethrin Squeeze- On Products". Claims implying heightened efficacy, or comparative statements, are considered false and/or misleading claims and are unacceptable.
- g. Modify the reapplication statement and "Three[3] Weeks Supply] or, [Six[6] Weeks Supply] or [Nine[9] Weeks Supply] or, [Twelve[12] Weeks Supply] or, [Three[3] Months Supply]" based on the new efficacy repellent claims [1 week] [8 days].
- h. List the U.S. fluid ounces equivalent in parenthesis under the net contents and directions for use.
- i. Provide a copy of the labeling for the applicator tubes. The minimum labeling required is the product name, keep out of reach of children, signal word, the EPA Registration Number and referral statement to the carton label for complete directions.

#### ACUTE TOXICITY REVIEW

STUDY	MRID	CATEGORY	CLASSIFICATION
Acute Oral	46299303	IV	Acceptable
Acute Dermal	46299304	IV	Acceptable
Acute Inhalation			Waived
Eye Irritation	46299305	IV	Acceptable
Dermal Irritation	46299306	IV	Acceptable
Dermal Sensitization	46299307	Positive	Acceptable

A copy of the toxicity and efficacy reviews are enclosed for your records.

3. Submit two (2) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Enclosures

12 27:04

## [MASTER CARTON/PACKAGE LABEL - FRONT PANEL]

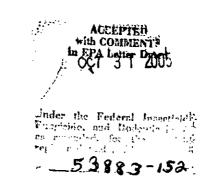
# **Cyper Horse Spot-On**

# **Biting Fly and Mosquito Protection**

- [> Kills [and] [&] Repels Horn Flies, Face Flies, Stable Flies, Horse Flies, Deer Flies, Black Flies, House Flies, Gnats [and][ &] Mosquitoes for up to [3 Weeks][21 Days]].
- [> Kills [and][&} Repels Biting [and][&][Nuisance] Flies for up to [3 Weeks][21 Days]].
- [> Kills [and][&] Repels Mosquitoes for up to [3 Weeks][21 Days]].
- [> Kills [and][&] Repels [Nuisance] Mosquitoes [and][&]Biting Flies for up to [3 Weeks][21 Days]].
- [> Kills [and][&] Repels Ticks on Horses].
- [> Effectively Kills [and] [&] Repels Horn Flies, Face Flies, Stable Flies, Horse Flies, Deer Flies, Black Flies, House Flies, Gnats [and][&] Mosquitoes for up to [3 Weeks][21 Days]].
- [> Effectively Kills [and][&] Repels Biting [and][&][Nuisance] Flies for up to [3 Weeks][21 Days]].
- [> Effectively Kills [and][&] Repels Mosquitoes for up to [3 Weeks][21 Days]].
- [> Effectively Kills [and][&] Repels [Nuisance] Mosquitoes [and][&]Biting Flies for up to [3 Weeks][21 Days]].
- [> Effectively Kills [and][&] Repels Ticks on Horses].
- [> Protects Horses from Horn Flies, Face Flies, Stable Flies, Horse Flies, Deer Flies, Black Flies, House Flies, Gnats [and][&] Mosquitoes for up to [3 Weeks][21 Days]].
- [> Protects Horses from [Nuisance][and][&] Biting Flies for up to [3 Weeks][21 Days]].
- > Protects Horses from Mosquitoes for up to [3 Weeks][21 Days].
- > Protects Horses from Ticks
- [> Protects Horses from [Nuisance] Mosquitoes [and][&] Biting Flies for up to [3 Weeks][21 Days]].
- [> One [Dose] [Treatment] Lasts up to [3 Weeks][21 Days]].
- [> Three [3] Weeks Supply]\*or, [Six [6] Weeks Supply]\* or, [Nine [9] Weeks Supply]\*, or, [12 Weeks Supply]\*, or [Three [3] Months Supply]\*
- [> Waterproof[!]].
- [> Prevents Mosquitoes that Transmit West Nile Virus from Feeding on Horses for up to [3 Weeks][21 Days]].
- [> Kills Mosquitoes, The Vector of West Nile Virus for up to [3 Weeks][21 Days]].

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[> Quick Action & Longest Acting].



# [MASTER CARTON/PACKAGE LABEL - FRONT PANEL CONT'D]

- [> Protects Against Biting Insects 50% Longer than Permethrin Squeeze-On's for Horses].
- [> Protects Against Biting Insects on Horses 50% Longer than Permethrin Squeeze-On Products].
- [> Works 50% Longer].
- [> Works 50% Longer than Permethrin Squeeze-On Products].
- [> Ready To Use].
- [> Ready To Use No Dilution Required].

#### **{LABELING NOTES:**

- 1) Product label may contain graphics (illustrations) depicting the product's use on horses, e.g., applying or streaking of product on horses as outlined under the "Directions For Use" Section of the product label.
- 2) Text or images in [] on this label denotes optional statements and/or images that may appear on front, back, sides, top or bottom of carton/applicator outer packaging and/or applicator labeling.
- 3) Due to the limited size of the carton/applicator outer packaging, the "Ingredient Statement" may need to be placed on the back carton/applicator outer packaging in order for it to appear "Prominently".

\*The weeks or months supply time indicated on the label will correspond to the number of application tubes contained the carton/packaging. Each applicator tube is equal to a 3-week supply. For example, a carton containing 4 x 9 cc applicator tubes may carry a statement for "3-Months" or "12-Weeks" Supply.

#### **ACTIVE INGREDIENT:**

Cypermethrin (CAS# 52315-07-8)	17.5%
OTHER INGREDIENTS:	82.50%
TOTAL:	100.0%

# KEEP OUT OF REACH OF CHILDREN CAUTION

See [Back][or][Side] Label Panel[s] for Additional Precautionary Statements

NET CONTENTS: 1 x 9 cc applicator, or

2 x 9 cc applicators, or

3 x 9 cc applicators, or

4 x 9 cc applicators, or

5 x 9 cc applicators, or

6 x 9 cc applicators, or

8 x 9 cc applicators

# [MASTER CARTON/PACKAGE LABEL - BACK/SIDE PANELS]

# ● FOR USE ON HORSES ONLY ● DO NOT USE ON FOALS LESS THAN THREE (3) MONTHS OF AGE ● DO NOT APPLY THIS PRODUCT TO HORSES INTENDED FOR SLAUGHTER OR HUMAN CONSUMPTION

#### READ THE ENTIRE LABEL BEFORE EACH USE.

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful is swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. FOR EXTERNAL USE ON HORSES ONLY. Do not apply this product to foals less than three (3) months of age. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing horses. Do Not apply this product to animals other than horses. Sensitivities may occur after using ANY pesticide product on horses. If signs of sensitivity occur bathe your horse with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID		
If in eyes:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	
If swallowed:	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have a person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>	
If on skin or clothing	<ul> <li>Take of contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15 to 20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	

#### **HOTLINE NUMBER**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-NNN for emergency medical treatment information.

## NOTE TO PHYSICIAN OR VETERINARIAN

This product contains the synthetic pyrethroid, Cypermethrin. Treat patient symptomatically.

# [MASTER CARTON/PACKAGE LABEL - BACK/SIDE PANELS CONT'D]

#### **ENVIRONMENTAL HAZARDS**

This product is highly toxic to fish and other aquatic organisms. Do not apply directly to water. Do not contaminate water when disposing of the applicator device.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label before each use.

Do Not apply this product to horses intended for slaughter or human consumption. Do Not apply this product to foals less than three (3) months of age.

How to Apply: This product is packaged in ready to use applicator tubes and does not require dilution. Hold the applicator tube with the top end pointing up and away from face and body. Snap off or remove the applicator tube tip with scissors. Invert the applicator tube and squeeze to apply product onto the horse. Follow the "cc" guide marks on the applicator tube and apply as follows:

- 1. Apply 2 cc on the poll taking care to keep away from the eyes and mucous membranes.
- 2. Apply as a "streak", 0.5cc on each side of withers (1cc total)
- 3. Apply as a "streak", 1cc on each side of hindquarters (2cc total)
- 4. Apply as a "streak", 1cc on front of each front leg below the knee (2 cc total)
- 5. Apply as a "streak", 1cc on the back of each hind leg below each hock on the gaskin muscle (2cc total)

# [ILLUSTRATION SHOWING HORSE & APPLICATION SITES]

Reapply every 3 weeks (21 Days) only as needed to maintain pest control.

#### STORAGE & DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a cool, dry area preferably locked and away from children and pets. Do not allow product to freeze by storing at temperatures below 32°F (0°C). Do not store in a manner that will adversely effect the applicator tube(s) or outer packaging.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Offer for recycling or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. You may also contact your local solid waste agency or 1-800-CLEANUP for disposal instructions.

### [WARRANTY

Control Solutions, Inc. warrants that his product conforms to the chemical description on the label. Control Solutions, Inc. neither makes nor authorizes any agent or representative to make, any other warranty of fitness of merchantability, guarantee or representation, express or implied, concerning this matter. Control Solutions, Inc.'s maximum liability for breach of this warranty shall not exceed the purchase price of the product. Buyer and user acknowledge and assume all risks and liabilities resulting from the handling, storage and use of this material which extend beyond the use of the product under normal conditions in accord with statements made on this label.]

[Control Solutions, Inc. is committed to providing high quality products. If you have questions or comments about this product, please write: Control Solutions, Inc., 5903 Genoa-Red Bluff, Pasadena, TX 77507-1041.]

Control Solutions, Inc. 5903 Genoa-Red Bluff Pasadena, TX 77507-1041 EPA Reg. No. 53883-RLE EPA Est. No.

[BAR CODE AREA]