

New York State Department of Environmental Conservation

Division of Solid & Hazardous Materials

Bureau of Pesticides Management, 11th Floor

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March 4, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Steve Rogosheske
Agent for Sergeant's Pet Care Products, Inc.
Regulatory & Scientific Consulting
1479 West Pond Road
Eagan, Minnesota 55122

Dear Mr. Rogosheske:

Re: Registration With Conditions of the Major Change in Labeling for the Active Ingredient Etofenprox as Contained in the Pesticide Products Sergeant's Gold Squeeze-On for Cats & Kittens, 2.2 to 5 lbs. (EPA Reg. No. 69332-3-2517) And Sergeant's Gold Squeeze-On for Cats & Kittens, over 5 lbs. (EPA Reg. No. 69332-3-2517)

The New York State Department of Environmental Conservation (Department) has completed a technical review of the applications and supplemental information submitted to date regarding registration of the above-referenced products in New York State. These products represent a major change in labeling for the active ingredient etofenprox (Chemical Code 128965).

The Department hereby accepts Sergeant's Gold Squeeze-On for Cats & Kittens, 2.2 to 5 lbs. (EPA Reg. No. 69332-3-2517) And Sergeant's Gold Squeeze-On for Cats & Kittens, over 5 lbs. (EPA Reg. No. 69332-3-2517) for registration subject to the following conditions:

- **The expiration date of Sergeant's Gold Squeeze-On for Cats & Kittens, 2.2 to 5 lbs. (EPA Reg. No. 69332-3-2517) And Sergeant's Gold Squeeze-On for Cats & Kittens, over 5 lbs. (EPA Reg. No. 69332-3-2517) coincides with the federal expiration date of March 1, 2006. If the USEPA grants an unconditional registration or extends the expiration date, your registration will continue until the expiration date on your certificate of registration.**
- **USEPA reviews and/or DERs for the acute, subchronic and developmental neurotoxicity studies and indoor dissipation and degradation studies must be submitted to this Department before March 1, 2006. Registration status is dependent upon USEPA's review and concurrence with the Department's evaluation of these same studies.**

The Department reviewed the application and supporting data submitted on behalf of Sergeant's Pet Care Products, Inc., by Steve Rogosheske, Regulatory & Scientific Consulting, to register the pesticide products Sergeant's Gold Squeeze-On for Cats & Kittens, 2.2 lbs. and under 5 lbs. (EPA Reg. No. 69332-2-2517) and Sergeant's Gold Squeeze-On for Cats & Kittens, 5 lbs. and over (EPA Reg. No. 69332-2-2517). These products contain the active ingredient etofenprox (2-(4-ethoxyphenyl)-2-methylpropyl-3-phenoxybenzyl ether). Both Sergeant's Gold Squeeze-On products are labeled for control of fleas, ticks and mosquitoes on cats and kittens. The proposed uses of these two products have been determined to represent a major change in labeling for the active ingredient etofenprox in New York State. Etofenprox was recently reviewed as a new active ingredient in the pesticide products Etofenprox Technical and 1% Etofenprox Aerosol. The two Sergeant's Gold Squeeze-On products also contain the currently registered active ingredient pyriproxyfen.

On an acute basis, the formulated product was not very toxic to laboratory animals by the oral or dermal routes of exposure. The United States Environmental Protection Agency (USEPA) waived the requirement for an acute inhalation toxicity study, since the results on a very similar formulated product indicated no significant toxicity by this exposure route. The Sergeant's Gold Squeeze-On product was shown not to be very irritating to rabbit skin or eyes and it did not cause dermal sensitization (tested on guinea pigs).

From 2002 through the present, the Department reviewed the active ingredient etofenprox. In that review, etofenprox was not very toxic, irritating and did not cause skin sensitization following acute exposures in laboratory animals. Also, etofenprox did not cause any significant neurotoxic (based on our review of the studies not yet evaluated by USEPA), developmental or reproductive effects. However, chronic exposures to etofenprox caused several noncancer effects at relatively low doses. The USEPA Office of Pesticide Programs calculated an oral reference dose (RfD) for etofenprox of 0.037 milligrams per kilogram body weight per day (mg/kg/day) based on a no-observed-effect level (NOEL) of 3.7 mg/kg/day in a chronic rat feeding study (increase in thyroid gland weights in male rats) and an uncertainty factor of 100. In addition, this active ingredient caused thyroid tumors in rats exposed over their lifetime. The USEPA classified etofenprox as a Group C, "possible human carcinogen" and developed a cancer potency slope factor for this chemical of 5.1×10^{-3} (mg/kg/day)⁻¹ for the quantification of risk. A current search of the toxicological literature did not find any significant new information on the toxicity of etofenprox.

The available information on etofenprox and the formulated product Sergeant's Gold Squeeze-On for Cats & Kittens indicates that they were not very acutely toxic, nor did the active ingredient cause significant neurotoxic, developmental or reproductive effects. Although etofenprox caused effects at relatively low doses in chronic toxicity studies and also caused thyroid tumors in rats, the expected exposure from using the Sergeant's Gold Squeeze-On product should not pose significant risks to users of this product. The Sergeant's Gold Squeeze-On product can be used indoors, but significant impacts to indoor air from etofenprox appear unlikely since this active ingredient has a low vapor pressure (2.4×10^{-4} millimeters mercury at 100 degrees Celsius) and it is applied in liquid form in small quantities (either 0.7 or 1.4 milliliters product, 409 or 818 mg etofenprox). Given the above, the Department does not object to the registration of Sergeant's Gold Squeeze-On for Cats & Kittens in New York State. However, this registration will be conditional, pending the USEPA's review and concurrence with the Department's recent evaluation of the acute, subchronic and developmental neurotoxicity studies on etofenprox.

There are no anticipated risks to fish, wildlife or groundwater resources since Sergeant's Gold Squeeze-On for Cats & Kittens, 2.2 to 5 lbs. (EPA Reg. No. 69332-3-2517) and Sergeant's Gold Squeeze-On for Cats & Kittens, over 5 lbs. (EPA Reg. No. 69332-3-2517) are labeled for indoor uses only. However, etofenprox is highly toxic to aquatic organisms. Any products containing this active ingredient bearing outdoor use patterns would require a full suite of environmental fate studies and USEPA DERs to support such uses.

Given the unique circumstances under which the New York State Department of Health (NYSDOH) reviewed the neurotoxicity and dissipation studies (i.e., no USEPA DERs), and that USEPA has not yet reviewed these data, the NYSDOH recommended that these products be registered conditionally pending USEPA's review and concurrence with their evaluation of these same studies.

REGISTRATION ACTION: The Department hereby accepts Sergeant's Gold Squeeze-On for Cats & Kittens, 2.2 to 5 lbs. (EPA Reg. No. 69332-3-2517) and Sergeant's Gold Squeeze-On for Cats & Kittens, over 5 lbs. (EPA Reg. No. 69332-3-2517) for registration subject to the following conditions:

- The expiration date of Sergeant's Gold Squeeze-On for Cats & Kittens, 2.2 to 5 lbs. (EPA Reg. No. 69332-3-2517) and Sergeant's Gold Squeeze-On for Cats & Kittens, over 5 lbs. (EPA Reg. No. 69332-3-2517) coincides with the federal expiration date of March 1, 2006.
- USEPA reviews and/or DERs for the acute, subchronic and developmental neurotoxicity studies and indoor dissipation and degradation studies must be submitted to this Department before March 1, 2006. Registration status is dependent upon USEPA's review and concurrence with the Department's evaluation of these studies.

Enclosed for your files is the Certificate of Pesticide Registration and New York State stamped "ACCEPTED" labels.

Please note that a proposal by Sergeant's Pet Care Products, Inc., or any other registrant, to register a product containing etofenprox, whose labeled uses are likely to increase the potential for significant exposure to humans or impact to the environment, would constitute a major change in labeled (MCL) use pattern. Such an application must be accompanied by a new application fee and meet the requirements specified in 6 NYCRR Part 326.17.

Please contact Samuel Jackling, Chief of 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

Enclosures

cc: w/enc. - N. Kim/D. Luttinger, NYS Dept. of Health
R. Zimmerman/R. Mungari, NYS Dept. of Ag. & Markets
W. Smith, Cornell University, PSUR