

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.state.ny.us

October 11, 2005

CERTIFIED MAIL **RETURN RECEIPT REQUESTED**

Ms. Beth Anderson
Gustafson, LLC
1400 Preston Road, Suite #400
Plano, Texas 75093

Dear Ms. Anderson:

Re: Registration of Storcide II (EPA Reg. No. 7501-202) containing the Active Ingredients Deltamethrin (chemical code 097805) and Chlorpyrifos (chemical code 059101). This represents a Major Change in Labeling for Deltamethrin.

The New York State Department of Environmental Conservation (Department) has completed its technical review of your application and data packages submitted on 2/24/05 and the occupational exposure and risk assessment submitted on 6/6/05, for the registration of the above-referenced product. Storcide II is an insecticide labeled for use in stored grains, and bins and warehouses where seeds and grains are stored. This proposed use is a new use pattern for deltamethrin in New York State. The application for Storcide II (EPA Reg. No. 7501-202) has been accepted for **registration** in New York State.

The active ingredient deltamethrin has been previously registered for control of insect pests in and around residential, industrial, and institutional structures and their immediate surroundings and for use on turf for both homeowner and commercial application. New York State has required buffer zones to limit impacts to fish and aquatic invertebrates (see letter dated 6/26/98 to Agrevo Environmental Health regarding the registration of DeltaGard G Insecticide Granules). The subject deltamethrin-containing product, Storcide II, is labeled for use in contained grain storage areas where labeled use of the product will not impact nontarget organisms or groundwater resources in New York State.

Storcide II contains 21.6% chlorpyrifos-methyl and 3.7% deltamethrin. The product is applied to grain or seed via automated spray system to give a deposit of 3 ppm of chlorpyrifos-methyl and 0.5 ppm of deltamethrin on the grain. The active ingredient, chlorpyrifos-methyl, is currently registered in New York State for this labeled use pattern.

The initial application for Optigard ZT was submitted on February 24, 2005. The Department notified Gustafson, LLC of an incomplete application via letter dated April 15, 2005. The Department required Gustafson, LLC to submit information on occupational and residential risk due to labeled use of the Storcide II product. This information was received by the Department on June 6, 2005. The application was declared complete as per Department letter dated July 8, 2005.

Pursuant to the review time frame specified in ECL §33-0704.2, a registration decision date of December 5, 2005 was established. The Department conducted the following technical review with regard to impacts to human health from the labeled use of the Storcide II product. Due to the indoor use pattern, groundwater and nontarget organism reviews were deferred. A review summary from the New York State Department of Health is provided below:

Human Health Review:

On an acute basis, Storcide II was not very toxic to laboratory animals by the dermal or inhalation routes of exposure. This pesticide product, however, was moderately toxic via oral exposure. In addition, Storcide II caused irreversible eye damage and moderate to severe skin irritation (tested on rabbits). It also was a skin sensitizer (tested on guinea pigs).

In the past, we reviewed deltamethrin as a new active ingredient for registration in New York State. Deltamethrin was moderately toxic to laboratory animals following oral acute exposure, but was not very acutely toxic by the dermal and inhalation exposure routes. This active ingredient was neither very irritating to animal eyes and skin nor was it a skin sensitizer. In addition, deltamethrin was not very toxic in chronic laboratory animal studies, nor did it cause oncogenic, genotoxic, or significant developmental/reproductive effects. The United States Environmental Protection Agency's (USEPA) Office of Pesticide Programs (OPP) established a reference dose (RfD) for deltamethrin of 0.01 milligrams per kilogram body weight per day (mg/kg/day) based on a no-observed-effect level (NOEL) of 1.0 mg/kg/day from a chronic feeding study in dogs (reduced body weight gain and chewing and scratching of extremities) and an uncertainty factor of 100. This RfD has not yet been adopted by the USEPA's Integrated Risk Information System (IRIS). A current search of the toxicological literature did not find any significant new information on the toxicity of deltamethrin.

The USEPA established tolerances for deltamethrin residues in or on wheat at 5.0 parts per million (ppm); barley (5.0 ppm); rice (2.5 ppm); and sorghum (0.5 to 1.0 ppm). The chronic population adjusted dose (cPAD) for deltamethrin is 0.0033 mg/kg/day and is based on the RfD of 0.01 mg/kg/day and an additional uncertainty factor of 3 to account for USEPA's "[C]oncern for the qualitative evidence of increased susceptibility observed in mice" (delayed ossification in fetuses at doses that did not cause maternal effects). The USEPA estimated that chronic dietary exposures to deltamethrin residues from a number of agricultural commodities, including those listed on the Storcide II label, would be less than 3.0% of the cPAD for the general U.S. population, less than 4.7% for all infants less than one-year old and less than 7.6% for children one- to two-years old. This chronic exposure analysis is based on anticipated residues from field trial values and percent crop treated information.

The USEPA conducted risk assessments for occupational exposures to both deltamethrin and chlorpyrifos-methyl (the second active ingredient of Storcide II). According to the USEPA, for deltamethrin, "No dermal endpoint was selected because no systemic toxicity via the dermal route was seen at the limit dose and therefore a dermal risk assessment was not required." For grain elevator workers treating 80,000 bushels of grain per day, the estimated margin of exposure (MOE) for inhalation exposure was greater than 19,000, whereas for grain storage workers treating walls of empty grain storage containers, the estimated MOEs ranged from 12,500 to 114,000. For these estimates, it was assumed that workers wore long-sleeved shirt, long pants,

chemical-resistant gloves and a respirator, as are required by the Storcide II product label. An absorption factor of 100% was used for inhalation exposures. The NOEL used for estimating these inhalation MOEs was 1 mg/kg/day from the chronic feeding study in dogs. With respect to chlorpyrifos-methyl as used in the Storcide II product, MOEs were estimated to be greater than 170 and greater than 320 for combined dermal and inhalation exposures for grain elevator workers (treating grain) and grain storage workers (treating walls of empty storage containers), respectively. An absorption factor of 3% was used for dermal exposures and 100% for inhalation exposures. The NOEL used for estimating these combined dermal and inhalation MOEs was 0.1 mg/kg/day based on inhibition of plasma cholinesterase at 90 days in a chronic/oncogenicity feeding study in rats. Generally, the USEPA considers MOEs of 100-fold or greater to provide adequate worker protection. In the case of deltamethrin, however, a MOE of 300-fold or greater may be a more appropriate basis of comparison given the uncertainties for fetal effects as accounted for in the cPAD derivation.

The available information indicates that deltamethrin is not very toxic following chronic exposure nor does it possess oncogenic, genotoxic or significant reproductive/developmental toxicological properties. In addition, both this active ingredient and the formulated product Storcide II are not very acutely toxic by the dermal or inhalation routes of exposure, but following oral exposure, both were moderately toxic. The formulated product caused irreversible eye damage, moderate to severe skin irritation to laboratory animals, and was a skin sensitizer. To mitigate these adverse effects, the Storcide II product label requires workers to wear goggles or face shield and impervious gloves when handling and to use a NIOSH-approved respirator. In addition, the estimated systemic risks to workers from use of the Storcide II product are within the range that is generally considered acceptable, and dietary exposure of the general public to deltamethrin residues on currently labeled crops is not expected to pose significant health risks.

Registration Summary:

As determined previously, the Department has some concern about the potential for the active ingredient to impact nontarget organisms and aquatic resources. Based on the previous review, any new product applications containing deltamethrin (such as for agricultural use) will be reviewed with a high degree of caution toward the protection of aquatic resources.

Enclosed for your record is a copy of the stamped accepted label and the Certificate of Registration for Storcide II (EPA Reg. No. 7501-202). Please note that a proposal by Gustafson, LLC, or any other registrant, to register a product that contains deltamethrin, and whose labeled uses are likely to increase the potential for significant impact to humans, nontarget organisms, or 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 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. Beth Anderson

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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

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