

**New York State Department of Environmental Conservation
Division of Solid and Hazardous Materials**

Bureau of Pesticides Management, 11th Floor
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November 28, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jim Baxter
State Regulatory Manager
Dow AgroSciences, LLC
9330 Zionsville Road
Indianapolis, Indiana 46268-1054

Dear Mr. Baxter:

Re: Registration of a Major Change in Labeled (MCL) Use Pattern for the Active Ingredient Sulfuryl Fluoride Contained in the Pesticide Product ProFume[®] Gas Fumigant (EPA Reg. No. 62719-376)

The New York State Department of Environmental Conservation (Department) has completed a technical review of the application (received February 24, 2005) and supplemental information submitted to date regarding registration of the referenced product in New York State. The Department also reviewed the amended labeling and supporting documents submitted by Dow AgroSciences, LLC (Dow Agro) on September 12, 2005. ProFume[®] Gas Fumigant (EPA Reg. No. 62719-376) contains the active ingredient sulfuryl fluoride (Chemical Code 078003).

ProFume[®] Gas Fumigant (99.8% sulfuryl fluoride) is a pressurized fumigant for control of rodent, insect, and other invertebrate pests. Labeled fumigation sites include nonresidential structures, food handling establishments (e.g., pet food facilities, bakeries, food production facilities, mills, warehouses, etc.), stationary transportation vehicles (railcars, shipping containers, trucks, etc., excluding aircraft and passenger railcars), temporary and permanent fumigation chambers, and storage structures. ProFume[®] is a federal RESTRICTED USE PESTICIDE due to acute inhalation toxicity of sulfuryl fluoride. Product is considered to be a methyl bromide replacement for some of the postharvest fumigation uses.

The use of ProFume[®] Gas Fumigant on raw agricultural and processed food commodities represents the first food use of sulfuryl fluoride in New York State.

The Department accepts ProFume[®] Gas Fumigant (EPA Reg. No. 62719-376) for registration as a “Restricted Use Pesticide” product in New York State. On or before November 30, 2007, Dow Agro must submit to the Department certain United States Environmental Protection Agency (USEPA) Data Evaluation Reports or detailed reviews as specified in the following risk assessment.

A human health risk assessment was conducted for ProFume[®] Gas Fumigant. Based on the enclosed structure use pattern and the product's chemical properties, ecological effects and environmental fate risk assessments were not conducted. The application package was deemed complete for purposes of technical review on July 8, 2005 following one determination of incompleteness (4/12/05). Pursuant to the review time frame specified in Environmental Conservation Law (ECL) §33-0704.2, a registration decision date of December 5, 2005 was established.

HUMAN HEALTH RISK ASSESSMENT: ProFume[®] Gas Fumigant contains no inert ingredients and is comprised almost solely of the active ingredient sulfuryl fluoride (there are 0.2% impurities in the product). Limited acute toxicity studies were conducted on ProFume[®] Gas fumigant because this pesticide product is a liquified gas and causes freezing of skin and eye tissues on contact. Consequently, the USEPA waived the requirement for acute dermal toxicity, dermal irritation, eye irritation and skin sensitization studies for federal registration of ProFume[®] Gas Fumigant, and classified it to not be very irritating or toxic via dermal exposure, nor to be a skin sensitizer. However, the USEPA classified this product as corrosive to the eyes. Acute oral and inhalation toxicity studies on the ProFume[®] product in laboratory animals showed that it is moderately toxic via oral exposure and very toxic via inhalation exposure.

In a two-week inhalation study and a 13-week inhalation study, both conducted on rabbits, sulfuryl fluoride caused brain damage at inhalation exposures equivalent to doses of 90 and 28 milligrams per kilogram body weight per day (mg/kg/day), respectively. The respective no-observed-effect levels (NOELs) were 30 and 8.5 mg/kg/day. The USEPA Office of Pesticide Programs calculated a reference dose (RfD) for sulfuryl fluoride of 0.003 mg/kg/day based on the NOEL of 8.5 mg/kg/day from the 13-week rabbit inhalation study and an uncertainty factor of 3,000 (10x to account for intraspecies differences, 10x to account for interspecies differences, 3x to account for using a subchronic study and an additional 10x to account for lack of a developmental neurotoxicity study). This RfD value has not yet been adopted by the USEPA Integrated Risk Information System (IRIS).

Sulfuryl fluoride caused some toxicity in chronic animal inhalation studies. In a one-year dog inhalation study, a decrease in body weight, dental fluorosis and a slight increase in alveolar macrophages in the lungs were observed at a dose of 20 mg/kg/day; the NOEL was 5 mg/kg/day. In a chronic inhalation/oncogenicity study in rats, dental fluorosis in males at 14 mg/kg/day, and renal toxicity and histopathological changes in the brain, liver and respiratory tract in females at 62 mg/kg/day were reported; the respective NOELs were 3.5 and 16 mg/kg/day. In a chronic inhalation/oncogenicity study in mice, sulfuryl fluoride caused decreased body weight gain, cerebral vacuolation and thyroid epithelial hypertrophy at a dose of 79.4 mg/kg/day with a NOEL of 19.8 mg/kg/day.

In developmental inhalation toxicity studies conducted in pregnant rats and rabbits, sulfuryl fluoride caused neither developmental nor maternal toxicity in rats at the highest dose tested, which was 243 mg/kg/day. In rabbits, a decrease in fetal body weight occurred at a dose of 86 mg/kg/day; the NOEL was 29 mg/kg/day. Maternal toxicity, characterized by a decrease in body weight and body weight gain was reported at the same dose (86 mg/kg/day) as the above- noted fetotoxic effect; the NOEL was also 29 mg/kg/day. In a rat multigeneration inhalation

reproduction study, a decrease in pup weight was reported at a dose of 108 mg/kg/day; the NOEL was 14 mg/kg/day. Parental toxicity, characterized by adverse lung effects (pale foci in the lungs, an increase in alveolar macrophages) occurred at 14 mg/kg/day with a NOEL of 3.6 mg/kg/day.

Sulfuryl fluoride did not cause oncogenic effects in either rat or mouse chronic inhalation studies. This chemical also gave negative results in several genotoxicity studies. Based on the lack of evidence for carcinogenicity in rats and mice, the USEPA classified sulfuryl fluoride as “not likely to be carcinogenic to humans.”

The USEPA established tolerances for sulfuryl fluoride residues in or on barley commodities at 0.05 parts per million (ppm) to 0.1 ppm; corn commodities (0.01 to 15 ppm); rice commodities (0.01 to 0.1 ppm); wheat commodities (0.02 to 40 ppm); sorghum (0.1 ppm); legumes (0.5 ppm); peanuts (0.5 ppm); tree nuts (3 ppm); herbs and spices (0.5 ppm); dried fruit (0.05 ppm); cheese (2.0 ppm) dried beef (0.01 ppm); and coffee (1.0 ppm). The chronic population adjusted dose (cPAD) for sulfuryl fluoride is 0.003 mg/kg/day and has the same basis as the RfD. The USEPA estimated that the chronic dietary exposure to sulfuryl fluoride would be 2.4% of the cPAD for the general U.S. population, 5.3% for all infants, 8.0% for children one to two years old, and 6.1% for children three to five years old. This chronic exposure analysis is based on the assumption that 40% of the commodities would be treated postharvest with the ProFume[®] product and using available data on anticipated and measured sulfuryl fluoride residue levels in food.

The USEPA conducted a risk assessment for short-, intermediate- and long-term inhalation exposures of workers to sulfuryl fluoride. Significant dermal exposure to sulfuryl fluoride was considered unlikely due to the use pattern of ProFume[®] Gas Fumigant (the product is dispensed as a pressurized gas from a steel cylinder through a hose into the interior of an enclosed sealed structure). In regard to inhalation exposures, the estimated margins of exposure (MOEs) for short-, intermediate- and long-term inhalation exposures of fumigators were 2,100, 650 and 650, respectively. For workers who enter the treatment chamber after the air concentration reaches a sulfuryl fluoride level of one ppm or less (as required by the label for unprotected workers), the respective estimated MOEs were 1,000, 300 and 300 for the above exposure periods. The NOEL used to estimate the short-term exposures to sulfuryl fluoride of both types of workers was 30 mg/kg/day (two-week rabbit inhalation study) and for intermediate- and long-term exposures it was 8.5 mg/kg/day (13-week rabbit inhalation study). For short- and intermediate-term exposures, the USEPA considered MOEs of 100-fold or greater to provide adequate worker protection, whereas for long-term exposures, protective MOEs were considered to be 300-fold or greater.

There are no chemical specific federal or New York State drinking water/groundwater standards for sulfuryl fluoride. Because it is not an organic compound, the general New York State drinking water standards for “principal organic compounds” or “unspecified organic contaminants” do not apply to sulfuryl fluoride. There is a New York State drinking water standard for fluoride, which is 2.2 milligrams per liter (10 NYCRR Part 5, Public Water Systems).

The available information on ProFume[®] Gas Fumigant indicates that this pesticide product has the potential to be very acutely toxic by inhalation exposure, and corrosive to eyes. Accordingly, to mitigate the corrosive properties to the eyes, the product has the precautionary statement, “Causes Irreversible Eye Damage” and requires workers to “Wear splash resistant goggles or full face shield when handling the liquid product during introduction of fumigant or when working around any lines containing fumigant under pressure.” To mitigate toxic effects from inhalation exposure, the ProFume[®] label requires applicators and workers who enter the fumigated area when the air level of sulfuryl fluoride exceeds one ppm to wear a NIOSH or MSHA approved positive pressure self-contained breathing apparatus. Sulfuryl fluoride did not demonstrate genotoxicity or carcinogenic properties. Although data from chronic and developmental/reproductive studies showed that this chemical has the potential to cause some toxicity, the estimated risks to workers from use of the ProFume product are within the range that is generally considered acceptable. Moreover, the ProFume product is a restricted use pesticide and has a comprehensive training/use manual that contains numerous precautions which helps ensure that workers handle the product appropriately. In addition, dietary exposure of the general public to residues of sulfuryl fluoride on foods that have been fumigated with this chemical is not expected to pose a significant health risk.

As conditions for federal registration of this pesticide product, USEPA requested that the registrant submit by January 26, 2006, the following information: 1) an inhalation developmental neurotoxicity study in rats; 2) data describing actual sulfuryl fluoride exposure to workers involved in fumigation and post-fumigation activities for various sites; and 3) data of sulfuryl fluoride residues in air from areas surrounding fumigation facilities. The New York State Department of Health (NYSDOH) requested that the registrant submit to the Department for NYSDOH review a copy of the USEPA Data Evaluation Record reports or if unavailable, a copy of the USEPA’s detailed reviews of this required information.

DISCUSSION: On November 15, 2005, Dow Agro provided the Department with confirmation that USEPA had waived the inhalation rat developmental neurotoxicity study. Dow Agro also provided study summaries of the occupational and residential exposure data (ten studies) submitted to USEPA on May 18, 2004. Dow Agro estimates that USEPA will review the air monitoring studies during the next 12 to 18 months. Therefore, Dow Agro must provide the Department with USEPA Data Evaluation Reports or detailed reviews of these studies by November 30, 2007.

REGISTRATION ACTION: The Department accepts ProFume[®] Gas Fumigant (EPA Reg. No. 62719-376) for registration as a “Restricted Use Pesticide” product in New York State. Enclosed for your files are the Certificate of Pesticide Registration and New York State stamped “ACCEPTED” labeling.

ProFume[®] Gas Fumigant (EPA Reg. No. 62719-376) contains a “YES” in the RESTRICTION column on the Certificate and is classified as a “Restricted Use Pesticide” product under rules and regulations 6 NYCRR Part 326.2. As such, this product is restricted in its purchase, distribution, sale, use and possession in New York State.

Mr. Jim Baxter 5.

According to Department regulations specified in 6 NYCRR 326.3(a): “It shall be unlawful for any person to distribute, sell, offer for sale, purchase for the purpose of resale, or possess for the purpose of resale, any restricted pesticide unless said person shall have applied for, and been issued a commercial permit.” If you require information regarding a commercial permit, please contact Maggie O’Neil, Chief, Pesticide Reporting and Certification Section, at (518) 402-8748.

The Pesticide Reporting Law (PRL) requires all certified commercial pesticide applicators to report information annually to the Department regarding each pesticide application they make. **Commercial pesticide retailers are required to report all sales of restricted pesticide products and sales of general use pesticide products to private applicators for use in agricultural crop production.** If no sales are made within New York State, a report still must be filed with the Department indicating this is the case. Information relating to the PRL or annual report forms is available at the Department’s website at <http://www.dec.state.ny.us> or from the Pesticide Reporting and Certification Section at (518) 402-8748.

Please note that a proposal by Dow AgroSciences, LLC, or any other registrant, to register a product containing sulfur fluoride, 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