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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAR 22 1989

MEMORANDUM

SUBJECT: Consideration of Conditional Registration for the Use of the New Chemical Sulfluramid (GX-071) in Indoor Bait Stations for Ant and Cockroach Control (EPA File Symbols 1812-GET,GEO,GGN) -Decision Memorandum-

FROM: Anne E. Lindsay, Director
Registration Division

TO: Douglas D. Campt, Director
Office of Pesticide Programs

Issue

Should the Agency grant a conditional registration to the subject three products which contain the new active ingredient sulfluramid under FIFRA section 3(c)(7)(C)?

Background

On May 4, 1988, Griffin Corporation applied for the registration of the technical product GX-071 containing the active ingredient sulfluramid (N-Ethyl Perfluorooctanesulfonamide) for use in formulating child resistant ant and roach bait stations. On June 24, 1988 Griffin Corporation applied for the registration of the two end-use products Raid Roach Controller II (EPA File Symbol 1812-GEO), and Raid Ant Controller II (EPA File Symbol 1812-GGN). Sulfluramid exerts its pesticidal activity by inhibiting oxidative phosphorylation.

Regulatory Status

All required science suport reviews for the Section 3 registration have been completed. Based on laboratory data, sulfluramid is of low acute mammalian toxicity. However, the compound causes male reproductive effects, namely decreased sperm production and a maturational arrest of spermatogonia, in dogs. Although the indoor use pattern and child resistant packaging would not warrant reproductive toxicity testing, these data were submitted to the Office of Toxic Substances under section 8(e) of TOSCA.

The Office of Pesticide Programs obtained the TOSCA review of this data via the 8(e) identifying number provided to OPP by the company. The assumption used to justify the toxicology data requirements, namely that there would be virtually no human exposure to the active ingredient, came into question when data submitted to the Agency on November 29, 1988 indicated that sulfluramid sublimes (i.e., it changes state from solid to gas) at elevated temperatures. After receiving additional data from the company regarding the vapor pressure and sublimation of sulfluramid and end-use product storage stability data, the Nondietary Exposure Branch of the Health Effects Division concluded that there would be relatively no human exposure to the active ingredient via sublimation.

Recommended Application Rates, Timing, and Amount

Raid Roach Controller II

12-15 1% baits in the kitchen for a total of 0.12-0.15 a.i.
2-4 1% baits in each bathroom for a total of 0.02-0.04 oz a.i.

-> Application (placement of bait station) repeated every 3 months.

Raid Ant Controller II

4 or more 0.5% baits depending on size of ant ifestation for a total of 0.02-0.04 oz a.i.

-> Application (placement of bait station) during infestation.

Toxicology Data

A battery of studies on the technical and end-use product as required by Pesticide Assessment Guidelines Subdivision F, 40 CFR Subpart 158.81 were submitted and reviewed by the Insecticide Rodenticide Support Toxicology Branch in the evaluation of sulfluramid and found to be acceptable in support of a conditional registration. However, the Mutagenicity Test on Sulfuramid in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay was unacceptable. The two other genotoxicity studies were acceptable and showed no mutagenicity. In addition, the Delayed Contact Sensitivity study was unacceptable due to a lack of positive controls. Both the Subchronic (90 day) Oral Toxicity in Beagle Dogs and the Male Canine Sterility Reversal

After Subchronic Oral Exposure studies, which have already been completed, must be submitted to OPP to determine the reversibility of the reproductive effect. See the attached Pesticide Fact Sheet for specific study results. There are four toxicology data gaps.

Ecological Effects Data

A battery of studies on the technical were submitted and reviewed by the Ecological effects Branch in the evaluation of sulfluramid and found to be in support of the technical and two indoor use registrations. Sulfluramid is highly toxic to both the Mallard duck and the Bobwhite Quail. In addition it is moderately toxic to the Rainbow Trout and highly toxic to Daphnia pulex. Although the trout and Daphnia studies were supplemental, the data were sufficient to support the indoor uses being registered.

Public Interest Findings

The subject ant bait insecticide has demonstrated equivalent to superior ant control as compared to hydramethylnon and propoxur. It is replacement option for a more toxic product, sodium arsenate, which has been given a Notice of Intent to Cancel and subsequent Administrative Hearing. The subject product has demonstrated superior efficacy in control of Pharaoh's ants which have been documented as carrying the following human pathogens: Salmonella spp., Pseudomonas aeruginosa, Staphylococcus spp., Streptococcus spp. and Clostridium spp..

The subject cockroach bait insecticide has demonstrated equivalent to superior efficacy against german cockroach as compared to chlorpyriphos, hydramethylnon, permethrin, propoxur, and sumithrin. It is in the public health interest to register this product because at least 18 species of domiciliary cockroaches, including most common species, naturally carry human pathogens, have been incriminated by experimental evidence to carry pathogens or are known to bite man. A list of human pathogens which have been naturally isolated from wild-caught cockroaches includes the following : four strains of

poliomyelitis virus; about 40 species of pathogenic bacteria, largely Enterobacteriaceae such as Salmonella typhimurium and the bacterial agent of Asiatic cholera; two pathogenic fungi, Aspergillus spp.; the Protozoa Entamoeba histolytica, Trichomonas hominus (Davaine), Giardia intestinalis (Lambl) and Balantidium coli (Malmsen), all suspected or proven agents of diarrhea or dysentery; yellow fever viruses; pneumonia; diphtheria; undulant fever; anthrax; tetanus; tuberculosis and cerebrospinal fever. The subject product represents a new class of insecticides, flouroaliphatic sulfonamides, which will provide a new avenue for cockroach resistance management. Therefore, the conditional registration of this new active ingredient is determined to be in the public interest.

Recommendation

The Registration Division recommends that the subject products containing the fluorinated sulfonamide GX-071 (sulfluramid) for control of cockroaches and ants indoors be conditionally registered under FIFRA Section 3 (c)(7)(C) with these conditional registrations to expire on September 15, 1989.

Concur: _____

Nonconcur: _____

Date: MAR 23 1989

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