Sulfluramid
Proposed Registration Review Final Decision
Registration Review Case 7411
June 2008

Approved by _____

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Please Note -

This proposed Registration Review Final Decision document summarizes the U.S. Environmental Protection Agency's current position based on the following documents:

1. U.S. EPA. Sulfluramid Summary Document, Registration Review Docket Case 7411. December 2007.

2. U.S. EPA. Sulfluramid Problem Formulation for Registration Review. September 27, 2007.

3. U.S. EPA. Sulfluramid: Human Health Assessment Problem Formulation Document in Support of Registration Review. September 13, 2007.

Additional supporting documents for sulfluramid can be found in the docket under EPA-HQ-OPP-2007-1082, which can be found on the internet at www.regulations.gov.

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) *Proposed Registration Review Final Decision* for sulfluramid and is being issued pursuant to 40 CFR §155.57 and 155.58. A registration review decision is the Agency's determination that a pesticide meets, or continues to meet the standard for registration in the Federal Insecticide Fungicide and Rodenticide Act (FIFRA).

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by EPA, based on scientific data showing that they will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment, and that products in the marketplace can be used safely. Information on this program is provided at: *http://www.epa.gov/oppsrrd1/registration_review/*.

In 2006, the Agency implemented the Registration Review program pursuant to FIFRA Section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

Pursuant to 40 CFR §155.50, the Agency formally initiated registration review for sulfluramid (case 7411) with the following timeline:

- December 19, 2007 - publication of the *Summary Document* in the docket for sulfluramid (EPA-HQ-OPP-2007-1082) for a 90-day public comment period. The *Summary Document* included the preliminary work plan, *Scoping Document*, and *Problem Formulation Document*.
- March 18, 2008 - close of the 90-day public comment period. The Agency received one comment from a private citizen, which did not impact the Agency's conclusions or timeline.
- May 12, 2008 - issuance of the *Final Work Plan* and the Agency's response to the public comment.

On October 26, 2007, the Agency issued a Final Rule in the *Federal Register* (FR) on the updated data requirements to support registration of conventional pesticides and updated definitions for conventional pesticide chemicals (72 FR 60934-60988). This rule became effective on December 26, 2007. The data and information evaluated for the *Summary Document* were considered in light of these requirements. This final rule does not trigger any further data requirements for currently registered pesticide products containing sulfluramid. However, if additional information is submitted that warrants further review, the Agency will then conduct any necessary risk assessment(s) prior to issuing the registration review final decision. The data and information evaluated to support sulfluramid as published in the *Summary Document* continue to support this pesticide registration as summarized herein. The

status of this and other registration review cases is available on *http://www.epa.gov/oppsrrd1/registration_review/reg_review_status.htm.*

Sulfluramid (N-Ethylperfluorooctanesulfonamide) is a perfluorinated compound, whose major degradate is perfluorooctylsulfonate (PFOS). Sulfluramid is currently only registered for use as a termiticide in pre-filled bait stations (including perforated tubes and stakes) that are placed around building perimeters (residential, food establishments, and other institutions) to manage termites. All products containing sulfluramid must be contained in child-resistant packaging (CRP). In 2001, the Agency completed human health and ecological risk assessments for products containing sulfluramid. Because of the potential toxicity concern resulting from bioaccumulation of PFOS in animals, as well as evidence of developmental and reproductive effects in toxicity studies, EPA negotiated with the technical and end-use registrants a phase-out of products containing sulfluramid, with all registrations set to expire by December 31, 2016. Additionally, all affected registrants agreed to discontinue producing any additional sulfluramid manufacturing-use product (MUP) and the acquisition or importation of any additional sulfluramid into the U.S.

At the beginning of the registration review process for sulfluramid, which began in 2007, the technical registrant had indicated that they exhausted their supply of technical sulfluramid. After holding discussions with the end-use registrants, the Agency renegotiated the phase-out terms for all remaining product registrations to expire by December 31, 2012. End-use registrants will be permitted to sell existing stocks for one additional year after the expiration of the product registrations. Currently, there are seven remaining registered end-use products that contain sulfluramid as an active ingredient. The Agency issued the product cancellation order for the last remaining manufacturing-use product registration on May 16, 2008 (73 FR 28465-28469).

II. SCIENTIFIC ASSESSMENTS

a. Human Health and Ecological Exposures and Risk Considerations

The Agency completed human health and ecological risk assessments in March and April 2001, respectively, to review the proposed (residential lawn and garden use) and registered products and uses of sulfluramid. The products and uses that were registered at the time included the following: ant and roach bait stations for use inside homes; termite bait stakes placed around building perimeters, fastened to infested masonry, or fastened to masonry of homes; granular formulations applied to outdoor residential turf to control ants, and; granular formulations applied to forestry sites to control ants.

In the sulfluramid human health assessment, available information showed that sulfluramid rapidly metabolizes to PFOS. PFOS cannot be further metabolized, and is excreted extremely slowly from the body. PFOS accumulates in various organs, primarily in the liver, and recirculates enterohepatically. Although exposure to PFOS was not directly associated with toxicity effects, EPA had concerns with the persistent systemic bioavailability, which can be up to several years. Evidence of developmental and reproductive effects was also seen in available sulfluramid toxicity studies. Some of the proposed uses and formulations of sulfluramid-

containing products resulted in potential risks of concern; specifically, exposure scenarios with children and occupational workers. EPA also performed an ecological assessment for products and uses of sulfluramid at that time, noting that PFOS can be readily mobile and persistent in the environment when applied. There is also the potential for PFOS to contaminate ground water. Some of the uses resulted in potential acute risk to birds and small mammals. In 2001, EPA negotiated a phase-out of products containing sulfluramid with all product registrations set to expire by December 31, 2016. Details regarding the phase-out are available in the *Summary Document*, which was issued December 2007. During the development of the Preliminary Work Plan for sulfluramid, EPA renegotiated the timeline for all remaining sulfluramid product registrations to expire four years earlier (December 31, 2012) than originally agreed to in the 2001 phase-out agreement.

For registration review, EPA reviewed the previous human health and ecological risk assessments completed in 2001 and current literature sources to determine if there are new data or other available information that would raise any additional risk concerns with the continued use of sulfluramid products during the phase-out period. Currently, the only remaining use of sulfluramid is for termite control in pre-filled bait stations and stakes around building (including residential) perimeters for outdoor use only; all other proposed and registered uses and products have since been cancelled. The Agency considered potential human health and ecological exposures and risk concerns for the remaining bait station use. Human exposure to sulfluramid from handling pre-filled bait stations is expected to be minimal. Additionally, no risks of concern from any potential exposure to children are expected, as all products containing sulfluramid are required to be packaged in child-resistant packaging (CRP). With the small amount of sulfluramid contained in the bait station and the unlikelihood of sulfluramid being widely dispersed into the environment, EPA does not expect significant movement of sulfluramid residues into surface water or ground water that would pose any human health (i.e., drinking water) or ecological risks of concern.

b. Endangered Species Assessment

The Agency expects that there will be minimal movement of sulfluramid out of the termite bait stations and into the environment. There is no information indicating that significant exposure would occur, specifically, to listed threatened or endangered species and/or effects on critical habitat based on a review of the available literature. As a result, the Agency has determined that the registered uses of sulfluramid will have "No Effect" on endangered or threatened terrestrial or aquatic species as listed by the U.S. Fish and Wildlife Service.

c. State Water Quality Concern

Sulfluramid is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act (CWA). EPA does not anticipate any significant water quality issues given its limited use and movement into the environment is expected to be minimal. The Agency invited the public to submit available water quality data on sulfluramid; however, no comments on water quality data were received. At this time, the Agency believes that current uses of sulfluramid-containing products will not pose any water quality concerns under the CWA.

d. Endocrine Disruption

EPA is required under Section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide product active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that it include evaluations of potential effects in wildlife. The Agency has no knowledge of sulfluramid being an endocrine disruptor. Consequently, endocrine-related concerns did not adversely impact the Agency's safety finding for sulfluramid. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program (EDSP) have been developed and vetted, sulfluramid may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

e. Incidents

The following excerpt of the Agency's review for potential human exposure incidents to products containing sulfluramid was taken from the most recent available human health assessment, dated March 27, 2001.

"Human incidence data for pesticide products may be useful to indicate trends in exposure especially when they contain active ingredients that have known acute effects. Based on the protracted serum half-life of the PFOS metabolite, it is possible symptoms of sulfluramid exposure would be delayed and may not be readily associated with the exposure... As expected for a chemical with acute effects that are not easily detected after exposure, a cursory analysis of incidence data does not show significant trends regarding reported acute health effects from children's exposure to baits containing sulfluramid."

Considering that the only remaining products are pre-filled bait stations in child-resistant packaging used outdoors, and that the amount of sulfluramid contained in each bait station is very small, acute effects from exposure to sulfluramid are expected to be minimal.

f. Trade Irritants

Through the registration review process, the Agency solicits information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Levels (MRLs) or disparities in key export markets, providing as much specificity as possible regarding the nature of the concern. In the case of sulfluramid, there are currently no registered food uses or residue tolerances established for sulfluramid. Additionally, there is no MRL established for sulfluramid. Therefore, the Agency does not anticipate current uses of sulfluramid posing concerns as a trade irritant.

g. Environmental Justice

EPA seeks to achieve environmental justice - the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income - in the development, implementation, and enforcement of environmental laws, regulations, and policies. At this time EPA does not believe that use of pesticide products containing sulfluramid will cause harm or a disproportionate impact on at-risk communities.

To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to pesticide products containing sulfluramid, compared to the general population. Please comment if you are aware of any sub-populations who may have higher exposure than the general population. The Agency will consider public comments and any additional information submitted in response to this docket to determine the need for new data and/or a new risk assessment. For additional information regarding environmental justice issues, please visit EPA's website at: *http://www.epa.gov/compliance/environmentaljustice/index.html*.

III. PROPOSED REGISTRATION REVIEW FINAL DECISION

The Agency's proposed registration review final decision is that no additional data are required at this time to support the registration of currently registered products that contain sulfluramid. The Agency has considered sulfluramid in light of the standard for registration and safety factors in FIFRA and FFDCA as amended by FQPA. EPA has found that there are not likely to be any unreasonable adverse effects to the U.S. population in general, to infants and children in particular, or to non-target organisms, from the use of products containing sulfluramid when currently required label instructions are followed. Based on all available information on sulfluramid, there are no new exposure concerns for currently registered products containing sulfluramid. Thus, the Agency has determined that no additional risk assessment or data are needed prior to the completion of the phase-out of the remaining product registrations.

Pursuant to 40 CFR §155.57 and 155.58, the Agency proposes that the standards for Registration Review have been met and that the registrations of currently registered products containing sulfluramid should be maintained through the end of the phase-out period. Table 1 lists all currently registered products that contain sulfluramid.

Table 1. Registered Sulfluramid Products

EPA Registration Number	Company Name	Product Name
279-3153	FMC Corporation	Firstline Termite Bait Station
279-3170		Firstline Termite Bait Tube Station
279-3171		Firstline Termite Bait Container Station
279-3196		Firstline GT Plus Termite Bait Station
9688-134	Chemsico, Division of United Industries Corporation	Chemsico Insect Bait A
9688-199		Chemsico Insect Bait SS
9688-209		Chemsico Insect Bait REP

IV. NEXT STEPS AND TIMELINE

Pursuant to 40 CFR §155.58, this proposed registration review final decision is being entered into the sulfluramid docket (EPA-HQ-OPP-2007-1082). A *Federal Register* notice will announce the availability of this proposed registration review final decision for sulfluramid and allow a 60 day comment period. If there are no significant comments or additional information submitted to the docket during the comment period that leads the Agency to change its decision, EPA will issue a final registration review decision for sulfluramid, Case 7411, which will be announced in the *Federal Register*. The Agency anticipates the final decision will be issued in the Fall of 2008.