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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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Background: The EH-2001 is a rodenticide with two active ingredients: alpha-olefin sulfonate (AOS) [the foam which is 17.6 % of the formulation] and ground mustard seed (MSP) [12.5% of the formulation]. Four additional ingredients have been identified as inerts: (1) [redacted] (2) [redacted] and (4) [redacted] The rodenticide's mode of action is asphyxiation by the foam. The mustard seed apparently is effective in speeding up the asphyxiation of the rodents by irritating the respiratory epithelium of the respiratory tract and possibly the lungs.

The registration of EH-2001 is being considered jointly by both the U.S. Environmental Protection Agency (EPA) and Canada's Pest Management Regulatory Agency (PMRA). Both PMRA and the EPA have previously reviewed information submitted for this product.

Discussion: In the July 19, 2001 responses to the Registrant, the EPA stated that in lieu of submitting the required data, that the registrant could submit scientific rationales to waive the requirements. Upon receiving the rationales, the suitability of any waiver would be assessed by

the Agency during a full evaluation. The EPA indicated that during the full evaluation, further clarification of minor information points may be required, but no additional data would be requested/accepted during full evaluation. Once all the reviews are complete and the results of one or more reviews indicate that further data are required, or if other issues are identified, the registrant was to be informed in a letter of evaluation deficiency. It is also recognized by the Agency that the proposed use of EH-2001 will not be the only source of AOS in the environment. EH-2001 and other sulfonates are anionic surfactants which are also used in soaps, industrial cleaners, etc.

This review addresses the Registrant response (MRID 45551105 - 3 Volumes) to the USEPA's review comments dated July 19, 2001. The Registrant has submitted summaries and copies of a number of research and other papers obtained from "Open Literature" sources (periodicals, books, etc.). Not all the topics (physicochemical properties, i.e., solubility, ultraviolet/visible light absorption, vapor pressure, specific gravity, dissociation constants) considered in the submission are EFED data requirements, but other Division or Office data requirements. Thus, EFED cannot evaluate that information. Other topics which may address some of the EFED data requirements (transformations, degradation pathways, rates of decline and formation, degradate identification) are also presented. Only those properties falling under EFED's data requirements can be considered.

It should be stated up front that because only the results of the "Open Literature" studies are presented, the studies cannot be scrutinized for QA/QC issues. This does not preclude the possibility that if the data were provided, some studies may be able to meet the Agency's QA/QC criteria. Two other factors increase the uncertainty of these studies. First, much of the literature submitted by the registrant is for sulfonates (Linear Alkyl Benzene sulfonates (LAS), and Alkyl Sulfates (AS)) other than Alpha-Olefin Sulfonates (AOS). Secondly, many of the studies do not adequately represent the environmental conditions present under the proposed use. Specifically, sulfonate degradation in sludge treated soil does not correspond to the placement of a foam within an animal burrow (subsoils rather than surface soils with less microbial activity) and less surface area initially in contact with soil. Also, as noted in the Agency's response on July 19, 2001, there is not a direct method of analysis capable of measuring AOS levels in the environment (soil and water). The current methods are either methyl blue active substance (MBAS) assay or radio-labeling (^{14}C). Therefore, there is only limited information available concerning AOS concentrations in the environment.

The information submitted by the registrant indicates that the degradation of sulfonate compounds generally occur fairly rapidly with the formation of a number of intermediate degradates. Many of the studies apply the sulfonate compound to soils that have been treated with sludge, thus, achieving maximum surface area contact with the compound. The proposed use, which places the sulfonate compound in an animal burrow, will have minimum surface area contact with soil thus, degradation rates could be considerably slower. The anaerobic degradation of the sulfonate compounds is also stated to be slower than aerobic degradation. Articles submitted by the registrant indicates LAS had detrimental effects on the vitality of soil

microorganisms. This could lead to increased persistence of AOS in soils when burrows are treated. These compounds also have high solubilities. They exist either in anionic or neutral charge, thus sorption may not be important. Thus, it may be very mobile. The sodium cation (Na^{1+}) can cause detrimental effects to soils. The registrant should evaluate and discuss what if any effects the addition of the sodium cation will have on the soil.

The information submitted by the registrant can be used as supplemental data, but there is still a need for certain core data requirements to be submitted to the Agency. Since the information submitted doesn't provide specific information on the persistence and mobility of the compound as it is proposed to be used, the Agency cannot do an accurate risk assessment.

Conclusion and Recommendations:

A portion of the Agency's mandate is estimate or determine levels of exposure and effects associated with the use of a pesticide. Currently, the Agency estimates exposure from monitoring data or from a number of computer simulation models (FATE, FIRST, SCI-GROW). In order to use these models, EFED must have an understanding of the degradation pathway, rates of decline and formation of parent and degradates, and mobility of the parent and degradates. Both of these processes contribute to the pesticide dissipation. The degradates must be defined, quantified and placed into a temporal scale so as to allow the Health Effects Division (HED) ability to assess potential for human health concerns and EFED to access possible ecological effects from the parent compound or from any or all the degradates.

The registrant has requested data waiver's for many of the EFED (Section 158) data requirements) in addition to other Division's data requirements. At this time, the Agency believes that based upon the proposed method of application and the currently available information, that the potential for ground water contamination is of the greatest concern. The proposed use sites (crops and locations) should be defined by the registrant, so that concern for ground water rather than surface water can be confirmed.

1. An analytical method be developed by the registrant, and validated by the EPA, that can measure the necessary parent and degradation products in both the soil and water medium.

2. Specifically, the following guideline studies should be conducted. It is recommended that a significant soil be selected from the anticipated use areas and then used in the study. The following studies should be conducted, Guidelines 163-1 (Soil Partition Coefficient), 162-1 (Aerobic Soil Metabolism), 162-2 (Anaerobic Soil Metabolism), and 164-1 (Terrestrial Field Dissipation). The species that should be considered are the parent compound, significant degradates, and degradates with a known or suspected health risk. It is suggested that the laboratory studies be conducted prior to the terrestrial field dissipation study. If the proposed use area, or addition uses are proposed that indicates that surface water could be a concern, then the following studies should be conducted: 162-3 (Anaerobic Aquatic Metabolism), 162-4 (Aerobic Aquatic Metabolism), and 164-2 (Aquatic Dissipation).