



**COMMENTS ON THE REREGISTRATION ELIGIBILITY DECISION
FOR PERMETHRIN
POSTED ON JUNE 28, 2006 - DOCKET EPA-HQ-OPP-2004-0385
SUBMITTED BY THE PERMETHRIN ISSUES REREGISTRATION TASK FORCE**

While some issues are still of concern, The PIRTF overall agrees with EPA's Reregistration Eligibility Decision and associated Risk Assessment. We present the following comments with respect to the RED and associated documents.

Introduction

The Permethrin Issues Reregistration Task Force (PIRTF), operating under the auspices of the Consumer Specialty Products Association, was formed on August 3, 2004 to ensure that registrants of non-agricultural uses of permethrin were represented through the reregistration process. There are currently 32 companies participating in the PIRTF.

FQPA

The PIRTF feels that a 1X FQPA safety factor provides an adequate safety margin considering the existing toxicology data demonstrating no evidence for increased susceptibility to infants and children.

Dietary Risk (Food and Drinking Water)

The PIRTF agrees with the dietary risk assessment.

Residential

The PIRTF feels that we have provided sufficient mitigation for those residential risks of concern to EPA.

The PIRTF is comfortable with much of the non-cancer Residential risk assessments. However, with respect to EPA's restrictions on crack and crevice sprays, again PIRTF believes EPA's contention that crack and crevice deposition rates are only 2 fold less than broadcast is an overly conservative assumption. Most crack and crevice sprays are used in areas such that little to no human exposure would occur, such as behind appliances, in cupboards and directly into void spaces. Existing data in the literature indicates crack and crevice sprays are 5-10 times less deposition and exposure to humans. (D.M. Stout and M.A. Mason, Atmospheric Environment 37 (2003) 5539-5549).

The PIRTF is comfortable with some of the cancer risk assessments, however, we still have issues with the highly conservative assumption of a 15% dermal absorption used in the cancer risk assessments. Current weight-of-the-evidence points to more realistic values of 2-5%.

We believe EPA is using an overly conservative assumption of nearly 10x and hope that the Agency will accept future data which may refine more accurately permethrin dermal absorption.

A very conservative dermal absorption factor of 15% was used in the risk assessments even though the data and information available to EPA justify use of a much lower percent dermal absorption factor. The weight of evidence from these data support the use of a 2% dermal absorption factor or at most, no higher than 3.2% (Driver H. J. and Ross H. J. January 23, 2005, "Permethrin: Review of Dermal Absorption Studies in Laboratory Animals and Humans," Valent Biosciences Corporation, Libertyville, IL 60048). In order to mitigate this concern, some consumer products are being impacted. A maximum rate of 0.25% permethrin in TRAs is being required. By using a 15% dermal absorption factor, this mitigation measure will lessen the efficacy of these formulations. In addition, a maximum rate of 0.50% permethrin in ready-to-use (RTUs) aerosol and pump spray products is being required. Total release aerosols and RTUs are valuable tools, especially to homeowners, for insect control, including disease vectors such as mosquitoes, fleas, and houseflies. The Agency should reevaluate its conservative approach in calculating the 15% dermal absorption factor, and consider the approach the OECD accepts, comparison of in vitro and in vivo dermal absorption tests with rat skin and human skin.

Misters

EPA is requiring many label changes to mitigate exposure to permethrin in both the home and work environment. We support the maximum use rates for outdoor mosquito misting systems and the required re-entry restrictions for the various application methods employed. These measures will greatly limit exposure to permethrin residues and protect the public from possible adverse affects.

Labeling for Misuse – Product Not Intended for Misting Systems

We remain concerned with the requirement that certain permethrin products which do not contain directions for use in outdoor mister systems must additionally contain the label statement, "Not for use in outdoor residential misting systems." We would suggest that the fact that the product is not labeled for use in outdoor misting systems, and already contains the EPA-required statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." should be sufficient to direct the consumer that the product may not be used in such systems. We think this additional labeling requirement is unnecessarily redundant of labeling statements already required, and reverses what we thought was a long-standing Agency policy of not labeling pesticide products for misuse. This sets a precedent which concerns us, as we consider the many uses for which pesticides are not intended and wonder how many other statements we may have to add to our labels addressing things that should not be done with a pesticide product. We would encourage the Agency to continue to focus on providing directions for use which clearly state what the product may be used for, rather than what it may not.

Carcinogenicity Rating

The carcinogenicity rating for permethrin was based on non-threshold effects modeled from an estimated systematic dose that includes all exposure routes. However, permethrin is neither a mutagen nor a genotoxic compound, and a non-threshold approach is not appropriate in determining carcinogenicity. We believe, like other pyrethroids that show liver effects without being mutagenic, that the data should be re-evaluated using a threshold approach.

Aggregate Risks

The PIRTF feels that we have provided sufficient mitigation for those aggregate risks of concern to EPA. EPA has indicated that certain aggregate risks for toddlers and adults are exceeded for short-term aggregate and aggregate cancer risk for food and drinking water combined with high contact post-application exposures. Again, the PIRTF believes that EPA has used highly conservative exposure assumptions for the indoor post-application calculations such as the crack and crevice assumption and dermal absorption mentioned above. Considering these highly conservative assumptions, PIRTF believes the aggregate exposures remain below a level of concern.

Cumulative

The PIRTF agrees with EPA's current approach regarding cumulative assessment.

Pharmaceutical uses

PIRTF agrees with EPA's approach with respect to dealing with inclusion of pharmaceutical use in the risk assessment. As indicated, "FDA has reviewed these estimates and determined that pesticide exposure in patients receiving treatment with a pharmaceutical permethrin drug product would fall within the expected range of exposure following treatment with permethrin drug product alone, and would not present an increased safety risk."

Down-the-Drain Assessments

The Agency used the Exposure and Fate Assessment Screening Tool (E-FAST), a down-the-drain model, to determine permethrin ecological impact related to domestic wastewater. This model relies on multiple assumptions and input parameters that are critical for the outcome. As stakeholders, we call for further information regarding these assumptions, input parameters, and the validation of this model. It is critical to understand the limitations of this model and its suitability and relevance to the assessment of permethrin presence in domestic waters.

Endocrine Effects

PIRTF agrees with EPA's conclusion that no data exists indicating permethrin is an endocrine disruptor.

Occupational Risks

The PIRTF feels that we have provided sufficient mitigation for those occupational risks of concern to EPA.

The PIRTF generally agrees with the Occupational risk assessment. However, we believe EPA still has used overly conservative assumptions with some use sites and the Task Force has committed to provide data to offset these conservative assumptions.

- The PIRTF feels low-pressure hand wand and ULV cold fogger are important PCO products. The risk assessment for this use area is again driven by the overly conservative assumption of 15% dermal absorption, which a group of registrants hope to address soon with additional data to refine the number.

Ecological Risks

The PIRTF agrees that the use of permethrin in mosquito abatement is extremely important. An article titled, "A Human-Health Risk Assessment For West Nile Virus and Insecticides Used in Mosquito Management," in Environmental Health Perspectives, Volume 114, No. 3, pages 366-372, states that ,

"Results from our risk assessment and the current weight of scientific evidence indicates that human-health risks from residential exposure to mosquito insecticides are low and are not likely to exceed levels of concern. Further, our results indicate that, based on human-health criteria, the risks from WNV exceed the risks from exposure to mosquito insecticides."

The PIRTF is concerned about the basis for the EPA claims made regarding urban run-off. The RED does not contain sufficient detail to adequately evaluate the veracity of the discussion regarding ecological risks. This is especially true for the models the Agency used. Moreover, the Agency appears to be relying on recently released data from Weston, et al. Although these data may be useful for hypothesis testing, we do not believe that such data should be uncritically applied in the context of the RED.

BEAD Assessment

PIRTF strongly disagrees with the BEAD assessment that permethrin can be replaced in the consumer market by other pyrethroids. Of those possible replacements listed by BEAD, only a few are residual pyrethroids. None listed are as economical currently as permethrin. The low price of permethrin based products allows availability to lower income groups to residually control public health pests in their homes and yards. Permethrin also has excellent repellency characteristics along with its residual activity. Easily affordable products would be few and far between should permethrin be lost in the residential marketplace.

Permethrin is an extremely valuable asset in pest control. It is used in agriculture to ensure a safe food supply and is also effective against a broad range of public health insects, including disease vectors such as mosquitoes (west Nile virus, encephalitis) and ticks (Lyme disease, rocky mountain spotted fever). The World Health Organization has estimated that Globally 200,000 children's lives are saved annually as a result from the use of insecticide

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treated tents, bed nets, clothing and curtains for preventing malaria (Lengeler, C., World Health Organization. Malaria Control Unit, UNICEF. The Africa Malaria Report 2003. Geneva: World Health Organization. 2003). Permethrin constitutes the majority of this use due to its low mammalian toxicity and efficacy against mosquitoes. It is also efficacious against many other public health pests such as roaches, fleas and flies. As such, it plays an important role in protecting the public health with less risk than alternatives such as organophosphates. Although EPA has been very conservative in its risk assessments, it has found that most uses are not of a public health or environmental concern. In those instances where a use was at or near a level of concern under very conservative worst-case scenarios, the mitigation measures being required are more than sufficient to protect the public health and environment.

Permethrin's combination of qualities such as persistency and repellency along with its efficacy characteristics permit it to be used in a manner that reduces overall pesticide use over time. This, along with permethrin's relative low mammalian toxicity, makes it a vital tool whose long and successful history of use should continue for many years to come. Compared to other residual pyrethroids, permethrin has less chance of causing paresthesia if someone accidentally comes in contact with permethrin. Permethrin is one of the very few residual pyrethroids without a cyano group, thought to be one of the contributing factors to paresthesia reactions.

EPA should carefully consider the benefits of permethrin and the implications of removing permethrin-based public health products from the residential marketplace. Permethrin is considered an affordable, less toxic replacement for organophosphates that were cancelled for residential use. Cancellation of permethrin-based products will limit the active ingredients available to control public health pests in residential environments and could even result in the reemergence of certain pests, as we have seen recently with bed bugs. Furthermore, removal of permethrin from the marketplace could accelerate the development of resistance to other residential insecticides.

Comments on the Letter from the American Academy of Pediatrics

Permethrin is very effective against a broad range of public health insects, including disease vectors such as mosquitoes (West Nile Virus, encephalitis) and ticks (Lyme disease, rocky mountain spotted fever). PIRTF believes that EPA has used very conservative assumptions in its risk assessment of permethrin treated clothing and agrees that the risks from wearing such clothing are well below any level of concern. The risk for anyone to contract disease from these disease carrying vectors which are controlled by permethrin is of far more concern.

Labeling

One general comment with respect to the label table is that it is somewhat confusing distinguishing which language needs to go on labels for which uses. Granted, the number of uses permethrin products can have is extensive and varied, and we hope that we can work further with the Agency to clarify how some of these labels should read. While it is important to have the right information on particularly consumer labels, it is also important that it be readable and not daunting for the consumer to read and to understand how to use the product correctly.

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