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Public Information and Records Integrity Branch (PIRB) (7502C)  
Office of Pesticide Programs (OPP)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave., N.W.  
Washington, DC 20460  
Attn: Docket ID Number OPP-2005-0042

Submitted via electronic mail

To Whom It May Concern:

**Docket No. OPP-2005-0042- Piperonyl Butoxide Risk Assessments**

The purpose of this letter is to comment on EPA's risk assessments for piperonyl butoxide (PBO), which were made available for public comment on April 27, 2005 (70 FR 21752). PBO is a synergist that increases the efficacy of other pesticides, most notably pyrethrins and pyrethroids. Tri-TAC is concerned that the risk assessments do not evaluate the potential adverse water quality impacts associated with sewer discharges of PBO, particularly PBO used in pet shampoos, head lice shampoos, and other indoor-use products. We are also concerned that the risk assessments for PBO only considered PBO alone, and not PBO in conjunction with the pesticides that it synergizes. As background, Tri-TAC is a technical advisory group for Publicly Owned Treatment Works (POTWs) in California. It is jointly sponsored by the California Association of Sanitation Agencies, the California Water Environment Association, and the League of California Cities. The constituency base for Tri-TAC collects, treats, and reclaims more than two billion gallons of wastewater each day and serves most of the sewered population of California.

**Comments on Indoor Uses, Including Pet Shampoos**

While the EPA risk assessments for PBO consider potential adverse water quality impacts arising from agricultural and mosquito abatement uses, they do not consider such impacts from PBO usage in pet shampoos and other indoor use products. The vast majority of pyrethrins are used in non-agricultural applications, including pet shampoos. According to EPA, only 5,000 to 10,000 pounds of PBO are used annually in the U.S. for application to agricultural crops, which an estimated 100,000 to

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200,000 pounds are used annually for non-crop uses.<sup>1</sup> Note that normal usage of pet shampoos includes a direct pathway to sewers, from rinsing of the shampoo after application. Even when pets are rinsed outdoors, the rinse water can enter storm drains or flow directly to creeks and rivers.

While some of the PBO discharged to sewers may be removed by wastewater treatment plants, there is no known data available on the amount removed. Some of the PBO may pass through the treatment plants into receiving water bodies. POTWs could be impacted if discharges of PBO lead to downstream water quality impacts, such as aquatic toxicity, either from the PBO alone or from the PBO acting in conjunction with other pesticides. Tri-TAC therefore requests that EPA evaluate potential adverse water quality impacts from sewer discharges of PBO.

### **Comments on Head Lice Treatment (Pediculicide) Uses**

Additionally, PBO is used in head lice shampoos containing pyrethrins. For example, RID Lice Killing Shampoo and RID Lice Killing Mousse both contain 0.33% pyrethrins and 4% PBO. When these shampoos are rinsed after use, they will flow directly to sewers. Although pediculicide uses of pesticides are not currently subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), they were subject to such regulation until 1979. Since pediculicides are considered to be drugs, they are also subject to the Federal Food, Drug and Cosmetic Act (FFDCA). On November 5, 1979 (44 Federal Register, 63749), EPA decided to exempt pediculicides from the requirements of FIFRA. The regulation of these products under both FIFRA and FFDCA was felt to be duplicative, as stated in the announcement of the exemption, "EPA and FDA concluded that the dual review of pesticide/new drug products offered solely for human use represents an expensive duplication of time and resources for both the Agencies and the sponsors of these products without any significant increase in benefits to public health and/or the environment. It is further concluded that regulations of these products solely by FDA under the FFDCA would adequately serve the intent of FIFRA."

Regulation under FIFRA and FFDCA is no longer duplicative. Since 1979, the degree of regulation under FIFRA has changed considerably, most notably with passage of the Food Quality and Protection Act of 1996 (FQPA). This statute requires EPA to review all pesticide registrations on at least a fifteen-year cycle (7 U.S.C. §136a(g)(1)(A)). The goal of this requirement is to ensure that all pesticides continue to meet up-to-date standards for safety, public health, and environmental protection. EPA has the authority to require data and take action if needed between registration cycles (7 U.S.C. §136a(c)(2)(B); §136a-1(d)(3)). No similar provisions exist under the FFDCA. Additionally, EPA has emergency suspension authority, which means a pesticide registration can be canceled immediately if there is an emergency, imminent threat to public health or the environment. (7 U.S.C. §136d(c)) This appears to be a much more direct and

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<sup>1</sup> EPA, Overview of the Piperonyl Butoxide Risk Assessments, May 4, 2005.

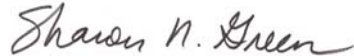
powerful tool to regulate pesticides when compared to the FDA's authority to simply require an Environmental Assessment in such circumstances.

Tri-TAC believes that EPA should reassert its control over pediculicides under FIFRA. As such action is beyond the scope of the action EPA is currently considering, EPA should, at minimum, consider the environmental impacts of these treatments in its current risk assessments. Under FIFRA, EPA has a statutory responsibility to ensure that pesticides are safe and effective for their intended uses and to prevent unreasonable adverse effects to man, other animals, and the environment from their usage (7 U.S.C. §136(bb), §136a(a), §136a(d)(2); §136d(b)). By ignoring the risks posed by PBO-containing head lice treatments, EPA is not fulfilling its statutory responsibility.

### Contact Information

Tri-TAC appreciates this opportunity to comment on the risk assessments for PBO. If you have any questions about this letter or require additional information, please contact Ann Heil by phone at 562/699-7411, extension 2950, or by e-mail at [aheil@lacsdsd.org](mailto:aheil@lacsdsd.org).

Sincerely,



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