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Public Information and Records Integrity Branch (PIRIB) (7502C)
Office of Pesticide Programs (OPP)
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1200 Pennsylvania Ave., N.W.
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Attn: Docket ID Number OPP-2005-0042

Submitted electronically

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

The purpose of this letter is to comment on EPA's revised risk assessments for piperonyl butoxide (PBO), which were made available for public comment on September 21, 2005 (70 FR 55383). PBO is a synergist that increases the efficacy of other pesticides, most notably pyrethrins and pyrethroids. Tri-TAC previously submitted comments regarding the PBO risk assessments on June 27, 2005; however, our concerns were not addressed in the revised risk assessments. We are concerned that the revised 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. Tri-TAC is 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.

Indoor Uses, Including Pet Shampoos

While the EPA revised 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, head lice shampoos, and other indoor use products. The vast majority of pyrethrins

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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; however, an estimated 100,000 to 200,000 pounds are used annually for non-crop uses.¹ The normal usage of pet shampoos results in rinsing of the shampoo after application, which is a direct pathway to the sewer. Even when pets are rinsed outdoors, the rinse water can enter storm drains or flow directly to creeks and rivers.

While some PBO discharged to sewers may be removed by POTWs, there is no known data available on the amount removed. Therefore, to be conservative in the risk assessments, EPA should assume that all PBO in the sewer system will pass-through POTWs without removal and be discharged into receiving waters. However, the Piperonyl Butoxide: EFED's Response to Public Comments and our Revised Ecological Risk Assessment (Memorandum) dated September 5, 2005 states, "EPA has no information to indicate that PBO from indoor/pet shampoo will pass through sewage treatment plants intact. The available data indicate that PBO is metabolized by soil microorganisms and photolyzed in water, thus it is reasonable to assume that it would be degraded in sewage treatment." This logic is flawed for several reasons.

First, EPA states in the Executive Summary of the Piperonyl Butoxide Environmental Risk Assessment (Risk Assessment) dated September 2005, "PBO degrades rapidly (8.4-hour half-life) in the environment by photolysis in water, and is metabolized by soil microorganisms (half-life 14 days in one experiment)." The detention time in wastewater treatment plants varies depending on the size of the plant, wastewater characteristics, treatment methods, and effluent discharge limits; however, it is reasonable to assume that in urban areas an activated sludge POTW producing secondary treated effluent has a detention time of approximately 8-10 hours. Therefore, using EPA's half-life numbers, during wastewater treatment only about half of the PBO received at POTWs would be degrading by photolysis and metabolism by soil microorganisms would be insignificant.

Secondly, EPA assumes PBO will be degraded by photolysis, which is a chemical process by which molecules are broken down by the adsorption of light. Typical treatment facilities at an activated sludge POTW are: headworks (bar screens, comminutors, etc.), primary sedimentation tanks, aeration tanks, secondary sedimentation tanks, and chlorine contact tanks. POTWs in urban areas usually cover the headworks and primary sedimentation tanks to control odors. Aeration tanks have a high turbidity due to the biological activity and mixing, thereby impeding light penetration. Secondary sedimentation tanks and gravity filters are typically uncovered, and some photolysis may occur. However, since these tanks are relatively deep, about 10 feet, light penetration would be limited to the wastewater near the surface of the tanks. Chlorine contact tanks are often covered to contain the disinfectant. Hence, Tri-

¹ EPA, Overview of the Piperonyl Butoxide Risk Assessments, May 4, 2005.

TAC disagrees with EPA's conclusion that PBO would be degraded during wastewater treatment by photolysis.

Therefore, in an activated sludge POTW, PBO degradation by photolysis and soil microorganisms would be limited. PBO passing through POTWs into receiving water bodies could impact POTWs if discharges of PBO lead to downstream 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.

Head Lice Treatment (Pediculicide) Uses

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. EPA responded to Tri-TAC's request to consider head lice treatment (pediculicide) use by stating in the Memorandum, "EPA has no information to indicate that PBO from head lice treatments will pass through sewage treatment plants intact. The available data indicate that PBO is metabolized by soil microorganisms and photolyzed in water, thus it is reasonable to assume that it would be degraded in sewage treatment." As discussed previously, Tri-TAC does not expect significant degradation of PBO during wastewater treatment by photolysis or soil microorganisms.

Furthermore, although pediculicide uses of pesticides are not currently subject to regulation under 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 the FIFRA. The regulation of these products under both the FIFRA and the 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 the FIFRA and the 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 powerful tool to regulate pesticides when compared to the FDA's authority to simply require an Environmental Assessment in such circumstances.

It is Tri-TAC's position 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 water quality risks posed by PBO-containing head lice treatments, EPA is not fulfilling its statutory responsibility.

Water Quality Model

In the Memorandum, EPA responded to Tri-TAC's request to consider potential adverse water quality impacts from the use of PBO in pet shampoos and other indoor use products as follows, "EPA/OPP does not have a peer-reviewed model for estimation of water impacts from urban use of pesticides. Adoption of the models suggested by the commenters (HSPF and SWMM) would require formal review by the Science Advisory Panel." However, EPA recently used the Exposure and Fate Assessment Screening Tool (E-FAST) as a screening model to evaluate permethrin exposure to aquatic organisms from consumer products in an Aquatic Exposure, "Down-the-Drain" Assessment conducted for the EFED Revised Risk Assessment for the Reregistration Eligibility Decision on Permethrin After Error Corrections Comments from the Registrant, Phase I dated July 12, 2005. Therefore, EPA does have an appropriate screening model to evaluate PBO exposure to aquatic organisms from pet shampoos, head lice shampoos, and indoor use products. We request that EPA conduct a similar Aquatic Exposure, "Down-the-Drain" Assessment for PBO and incorporate the results into the revised risk assessments.

Tri-TAC provided comments to EPA about the method used to translate wastewater treatment plant discharge concentrations from E-FAST into acute and chronic surface water concentrations and the use of a daily per capita mass discharge rate to calculate acute surface water concentrations used in the Aquatic Exposure, "Down-the-Drain" Assessment for permethrin. Even with the conservation assumptions used by EPA, the model results show that acute and chronic levels of concern for aquatic organisms were exceeded as a result of "down-the-drain" uses of permethrin. This result is significant because POTWs do not have the ability to regulate discharges of pesticides; however,

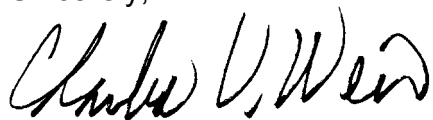
POTWs are required to meet effluent aquatic toxicity standards in National Pollutant Discharge Elimination System (NPDES) Permits. Tri-TAC requests that EPA conduct an analysis for the “down-the-drain” uses of PBO, especially since EPA states in the Risk Assessment that PBO has an “acute risk to amphibians, freshwater invertebrates and freshwater fish” and a “chronic risk to freshwater invertebrates and freshwater fish” from agricultural uses. In addition, if the model shows that acute and chronic levels of concern for aquatic organisms are exceeded, Tri-TAC requests that EPA propose mitigation measures for PBO during reregistration.

In conclusion, POTWs need EPA’s assistance to protect surface waters from contamination from PBO. As previously discussed, POTWs are required by NPDES permits to meet aquatic toxicity standards but do not have the authority to regulate pesticides. Tri-TAC requests EPA conduct an Aquatic Exposure, “Down-the-Drain” Assessment, similar to the analysis performed for permethrin, to evaluate potential aquatic toxicity impacts from the use PBO in consumer products with pathways to the sewer.

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 Ms. Preeti Ghuman by phone at (562) 699-7411, extension 2904, or by e-mail at pghuman@lacsdsd.org.

Sincerely,



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