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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-2004-0348

Submitted electronically

Docket No. OPP-2004-0348- Malathion Revised Risk Assessments

The purpose of this letter is to comment on EPA's risk assessments for malathion, which were made available for public comment on September 23, 2005 (70 FR 55839). Malathion is a non-systemic, broad-spectrum organophosphate pesticide with agricultural, residential, and wide area pest eradication uses. Malathion is also used as the active ingredient in a pharmaceutical product for the control of head lice. Tri-TAC is pleased that all pet and indoor uses of malathion will not be reregistered and request EPA to verify that these uses are removed from product labels. However, we are concerned that the revised risk assessments do not evaluate the potential adverse water quality impacts associated with sewer discharges of malathion from head lice treatments. In addition, Tri-TAC is concerned that the ecological risk assessments have not been updated since 2000 to include current methodologies. Furthermore, the ecological risk assessments should include all required aquatic toxicity test results and use current label use rates, intervals, and allowed number of seasonal applications. 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.

Head Lice Treatments

Malathion is used as the active ingredient in a pharmaceutical product for the treatment of head lice under the trade name Ovide Lotion, 0.5%. In the

Overview of Malathion Risk Assessment (Overview) dated September 2005, EPA states: "Ovide Lotion is marketed in 2 fl. oz. bottles and is only available through a doctor's prescription. Patients are directed by the label to use Ovide Lotion topically, by applying it to the scalp hair, leaving it on the patient (uncovered) for 8-12 hours, then washing it off." The normal use of this product causes malathion to be discharged directly into sewers. While the EPA revised risk assessments consider human health risks from the pharmaceutical use of malathion, the ecological risk assessments do not consider potential adverse water quality impacts arising from head lice treatments.

Tri-TAC is concerned about the discharge of malathion into sewers. In the Overview EPA states, "Malathion is toxic to aquatic organisms. Risk quotients above the Agency's level of concern for nontarget organisms result from low application rates." In addition, several fish kill incidents have been attributed to malathion. Tri-TAC requests that EPA conduct an Aquatic Exposure, "Down the Drain Assessment", similar to the analysis conducted for permethrin[1], to evaluate the potential impacts to aquatic organisms from the pharmaceutical use of malathion. In the Aquatic Exposure, "Down-the-Drain" Assessment for malathion, EPA should also consider the effects of malaoxon, the more potent oxygen analog of malathion, on aquatic organisms because in the Overview EPA states that due to fate and chemistry malathion converts to malaoxon during the chlorination process. Most POTWs utilize chlorination for disinfection; therefore, malathion received at POTWs may be converted to malaoxon during wastewater treatment.

Tri-TAC has provided comments to EPA about the method used to translate wastewater treatment plant discharge concentrations from the Exposure and Fate Assessment Screening Tool 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 conservative 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. If the Aquatic Exposure, "Down-the-Drain" Assessment shows that acute and/or chronic levels of concern for aquatic organisms are exceeded from the pharmaceutical use of malathion, Tri-TAC requests that EPA propose mitigation measures for malathion during reregistration.

[1] EPA, EFED Revised Risk Assessment for the Reregistration Eligibility Decision on Permethrin After Error Corrections Comments from the Registrant, Phase I, July 12, 2005

Ecological Risk Assessments

The ecological risk assessments for malathion have not been revised since May 2000. EPA acknowledges in the Memorandum: Status of Ecological Risk Assessment for Malathion dated February 3, 2005, "Since the completion of the malathion assessment in 2000 additional policies and guidance have been developed for ecological risk assessment in the Environmental Fate and Effects Division. Changes include the availability of modified runoff modeling scenarios and the use of literature searches conducted for the ECOTOX database. Upon review of the risk assessment and consideration of the updated guidance and policy, it has been determined that the conclusions of the risk assessment and characterization of risk from malathion's uses are accurate and would not be expected to change with new modeling and further consideration of the literature." Tri-TAC disagrees with this statement for several reasons. First, by using updated policies and guidance, the results of the ecological risk assessments may not change; however, the intensity of the risks to organisms (the magnitude above or below the levels of concern) may change significantly.

Furthermore, in the introduction of the Environmental Fate and Effects Chapter of the EFED Environmental Risk Assessment for the Malathion Reregistration Eligibility Document dated May 1, 2000, EPA states, "Worst case risk presumptions will be based on the maximum labeled rates, maximum permitted seasonal applications and minimum recommended intervals for these use patterns." However, in the risk assessments EPA used "assumptions of lower use rates, longer intervals, and limited numbers of seasonal applications" which "may lead to the prediction of lower risk potential" due to agreements with the registrants to revise the malathion labels. EPA states that the decision to use lower application rates in the risk assessments "will impact the currency of the present assessment for malathion impacts on wildlife and aquatic organisms." EPA further states, "…application restrictions and mitigation measures may not be implemented for several years pending final agreements with the registrants." Since it has been five years since the risk assessments were completed, the risk assessments should be revised to reflect current application rates, application restrictions, and mitigation measures stated on the labels to present an accurate assessment of malathion impacts on wildlife and aquatic organisms. In addition, EPA should conduct the "additional environmental assessment and review" required for "any labels which exceed the rates or permitted maximum seasonal applications, or that specify minimum application intervals which are less than the rates presented" in the risk assessments.

Finally, the risk assessments have not been updated to include required chronic toxicity test results for freshwater and estuarine/marine fish. EPA states: "A freshwater fish full life-cycle test using the TGAI is required for malathion because the end-use product is intended to be applied directly to water and is expected to be transported to water from the intended use sites…A satisfactory full life cycle test has not been submitted." In addition, "An estuarine/marine fish early life stage or life-cycle test using the TGAI is

required for malathion due to the application of malathion for mosquito and medfly control near estuarine habitats and use on crops associated with areas near these habitats. This study may be waived if further modeling results indicate that EEC levels in estuaries will not exceed the early life stage NOEC levels for a freshwater species." Tri-TAC is not clear on the technical basis for waiving the estuarine/marine chronic toxicity test because the freshwater early life stage NOEC levels are not exceeded, since estuarine/marine and freshwater species are different. We are interested in both the freshwater and estuarine/marine fish chronic toxicity test results since POTWs discharge to both types of receiving waters. Tri-TAC requests that EPA require both the freshwater and estuarine/marine chronic toxicity test results from the registrants, and include the results in revised risk assessments, prior to the reregistration of malathion.

Regulation of Head Lice Treatments

Malathion is used in head lice treatments that are applied directly to humans. When these treatments are rinsed after use, they will flow directly to sewers. 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.

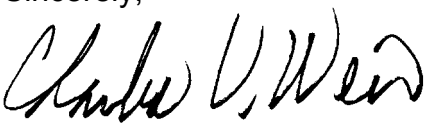
It is Tri-TAC's position that EPA should reassert its control over pediculicides under FIFRA. As such action is beyond the scope of the action EPA is currently considering, EPA should, at minimum, consider the environmental impacts of these treatments in its revised risk assessments. Under FIFRA, EPA 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 malathion-containing head lice treatments, EPA is not fulfilling its statutory responsibility.

In conclusion, POTWs need EPA's assistance to protect surface waters from further contamination from malathion. 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 that EPA conduct an Aquatic Exposure, "Down-the-Drain" Assessment, similar to the analysis performed for permethrin, to evaluate potential aquatic toxicity impacts from the pharmaceutical use of malathion.

Contact Information

Tri-TAC appreciates this opportunity to comment on the risk assessments for malathion. 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@lacsd.org.

Sincerely,



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