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Office of Pesticide Programs (OPP)
Regulatory Public Docket (7502P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001
Attn: Docket ID Number EPA-HQ-OPP-2004-0348

Submitted Electronically to Neil Anderson: anderson.neil@epa.gov

Docket No. EPA-HQ-OPP-2004-0348 - Malathion Reregistration Eligibility Decision

The purpose of this letter is to comment on EPA's Reregistration Eligibility Decision for Malathion (RED) that was made available for public comment on November 29, 2006 (71 FR 69114). 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, the only indoor use eligible for reregistration. Tri-TAC commented on the Malathion Revised Risk Assessments on November 22, 2005 and requested that EPA evaluate the potential water quality impacts associated with sewer discharges of Malathion from head lice treatments. Tri-TAC is pleased that EPA utilized the Exposure and Fate Assessment Screening Tool (E-FAST) in a down-the-drain assessment to evaluate potential aquatic impacts from the pharmaceutical use of Malathion prior to issuing the RED. Since the current procedures used in down-the-drain assessments do not fully analyze the potential impacts to aquatic organisms from the discharge of pesticides into sewers, Tri-TAC would like to work with EPA to refine the methodology for future down-the-drain assessments. 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.

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Tri-TAC reiterates our appreciation for EPA's effort in conducting a down-the-drain assessment prior to issuance of the RED. The remaining indoor use of Malathion is a pharmaceutical product for the treatment of head lice under the trade name Ovide[®] Lotion, 0.5%¹. In the RED, EPA evaluated the potential impacts from the pharmaceutical use of Malathion and estimated the risk quotients to non-target aquatic organisms to be very low based on the 2000-2001 production volume of Ovide[®]. EPA also states that since Ovide[®] production has increased since 2000-2001 by approximately three-fold, estimated environmental concentrations from down-the-drain sources are not expected to be greater than 1.0×10^{-4} ppb.

In the down-the-drain assessment on page 91 of the RED, EPA states that the 2000-2001 production volume of 100 kg/year was used in the E-FAST model to estimate environmental concentrations (acute 3.55×10^{-5} ppb and chronic 2.73×10^{-6} ppb). It is unclear why 100 kg/year, instead of 283 kg/year², was used in the analysis when on page 57 of the RED EPA states that current production volume is approximately three times the 2000-2001 production volume. Tri-TAC recommends that pages 57 and 91 be revised using the current production volume and state that the down-the-drain assessment estimates an acute estimated environmental concentration of 1.00×10^{-4} ppb based on the high-end stream dilution factor and a chronic estimated environmental concentration of 7.73×10^{-6} ppb based on the median stream dilution factor.

Since Tri-TAC is familiar with the E-FAST model, we were able to follow the methodology used in the down-the-drain assessment even though the detailed calculations were not presented. Tri-TAC recommends for clarity that calculations be included in future documents, or at least included in an attachment.

Tri-TAC has previously submitted general comments to EPA regarding our concerns with E-FAST. In our comments, Tri-TAC has requested the technical basis for assuming the surface water concentrations obtained from the 10th and 50th percentile stream dilution factors as acute and chronic concentrations in national down-the-drain assessments. Some publicly owned treatment works (POTWs) discharge to effluent dominated receiving waters, providing essentially the only source of water to a surface water body during dry periods, and the National Pollutant Discharge Elimination System (NPDES) permits for these facilities do not include a stream dilution factor. In addition,

¹ On page 37 of the RED, EPA incorrectly states that the concentration of Malathion in Ovide[®] Lotion is 0.05%. The concentration of Malathion in the lotion is actually 0.5%. The correct concentration was used in the Overview of Malathion Risk Assessment dated September 2005.

² 283 kg/year was back-calculated using the E-FAST model and EPA's statement on page 57 of the RED that "Since Ovide[®] production has increased since 2000-2001 by approximately 3-fold, estimated environmental concentrations from down-the-drain sources are not expected to be greater than 1.0×10^{-4} ppb." Using 283 kg/year as the production volume in the E-FAST model, the high end time-averaged surface water concentration is estimated to be 1.0×10^{-4} ppb.

other facilities in the country do not have dilution credits in their NPDES permits for other environmental reasons. Therefore, EPA should not include stream dilution factors in national down-the-drain assessments for pesticides.

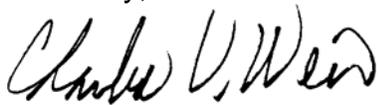
For down-the-drain assessments, EPA should use E-FAST to calculate a median surface water concentration without a stream dilution factor for use as the chronic estimated environmental concentration in the risk analysis. For the acute estimated environmental concentration, EPA should calculate a surface water concentration assuming a local high-end scenario appropriate for the pesticide. For example, a high-end scenario would be a concentrated mass loading of Malathion to a POTW following an outbreak of head lice at an elementary school. The surface water concentration from the high-end scenario, without a stream dilution factor, should be used as an acute estimated environmental concentration in the risk analysis. These simple modifications to the procedures for down-the-drain assessments would result in better assessments of the potential impacts to aquatic organisms.

Tri-TAC would like to work with EPA's Offices of Pesticide Programs and Wastewater Management to develop an improved wastewater discharge methodology to evaluate the potential impacts to aquatic organisms from pesticides discharged to sewers using the April 2006 version of E-FAST. This methodology would include an analysis of the input parameters and scenarios needed to generate representative surface water concentrations from the use of pesticides discharged to sewers. Development of a methodology would be beneficial to both EPA and POTWs to evaluate the impacts of pesticides during Registration Review.

Tri-TAC appreciates that EPA evaluated the potential environmental impacts from the pharmaceutical use of Malathion in the RED. EPA should continue this practice during Registration Review by including both indoor and pharmaceutical uses in down-the-drain assessments. Even though pediculicides are considered drugs and are regulated under the Federal Food, Drug, and Cosmetic Act, EPA has a responsibility to evaluate the water quality risks posed by the use of pesticides that discharge to sewers.

Tri-TAC appreciates this opportunity to comment on the RED. 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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Chair, Tri-TAC

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Office of Pesticide Programs

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