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Attn: Docket No. OPP-2004-0305Ms. Tobi Jones

Submitted electronically

Docket No. OPP-2004-0305 - Comments on the Reregistration Eligibility Decision for Poly(hexamethylenebiguanide) hydrochloride

The purpose of this letter is to comment on EPA's Reregistration Eligibility Decision (RED) for poly(hexamethylenebiguanide) hydrochloride (PHMB), which was made available for public comment on March 22, 2006 (71 FR 14514). Tri-TAC is concerned that the revised risk assessments do not evaluate the potential adverse water quality impacts associated with sewer discharges of PHMB, particularly PHMB used in swimming pools and spas (hereon collectively referred to as pools) and other indoor-use products. Tri-TAC requests that EPA require acute and chronic aquatic toxicity test data for estuarine/marine organisms and chronic aquatic toxicity test data for freshwater and estuarine/marine fish and invertebrates. In addition, Tri-TAC requests that EPA conduct an Aquatic Exposure, "Down the Drain Assessment", similar to the analysis conducted for permethrin¹, to evaluate the potential impacts to aquatic organisms associated with PHMB discharges to publicly owned treatment works (POTWs). If this assessment predicts adverse effects, Tri-TAC requests that EPA require mitigation measures as a condition of reregistration. 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.

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.

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Risk Assessments

According to EPA's Poly(hexamethylenebiguanide) hydrochloride (PHMB) Risk Assessment for the Reregistration Eligibility Decision dated February 14, 2005, approximately 95% of the use of PHMB is for pools. A small amount of PHMB is also used to preserve cut flowers, sanitize hard surfaces, and prevent biological growth in oil recovery and industrial facilities. Despite the high percentage of use of PHMB in pools, where PHMB is applied directly to the pool as a disinfectant, EPA's risk assessments assume that no PHMB will enter surface waters. In the PHMB Summary dated August 26, 2004, EPA states "The labeled uses of PHMB are not expected to result in significant environmental exposure; therefore, adverse effects on terrestrial and aquatic species, including endangered species, are not anticipated when registered products are used in accordance with the label. The high toxicity of PHMB to freshwater organisms is of concern in the event of a spill or misuse of the product. Product labeling indicates that the chemical is toxic to fish and that discharge into water should not occur except in accordance with NPDES requirements." This logic is flawed for several reasons.

First, Tri-TAC disagrees with EPA's assumption that PHMB will not enter surface waters. Wastewater is produced from pools when the pool is emptied, during overflows in rainy periods, and when filter backwash is discharged. Typically pools are drained to the sewer or the storm drain every several years in order to perform maintenance. Newer pools are typically plumbed to sewer cleanouts and thus drain their wastewater to the sewerage system.² Discharge to a storm drain releases the water (and any associated PHMB) directly to surface water, typically in a matter of minutes. Discharge to a sewer system sends the water (and any associated PHMB) to a POTW, which in turn, often discharges to surface water. Individual National Pollutant Discharge Elimination System (NPDES) permits are not required for pool discharges (including residential pools). Although such discharges could cause or contribute to violations of NPDES permits, controlling such discharges is difficult if not impossible, particularly from residences. Wastewater containing the pesticide can also be discharged into sewer systems from washing cut flowers and cleaning indoor surfaces treated with PHMB.³

² County Sanitation Districts of Los Angeles County, *Chloride Source Identification/Reduction, Pollution Prevention, and Public Outreach Plan*, November 2005.

³ The California Department of Pesticide Regulation commissioned a report that explored the linkage between indoor pesticide use and releases to surface waters. See Appendices E, F, and G of TDC Environmental, *Diazinon & Chlorpyrifos Products: Screening for Water Quality Implications*, May 15, 2001, available on the Internet at <http://www.cdpr.ca.gov/docs/sw/contracts/pstscrn.pdf>.

Although the Risk Assessment presents very limited aquatic toxicity data, the available data include a relatively low 96-hour LC50 of 25 parts per billion (ppb) for rainbow trout. If a typical 15,000-gallon pool was treated with PHMB to the 50 part per million concentration recommended on the product label, it would contain enough PHMB to pollute 30 million gallons of water to the 25 ppb rainbow trout LC50. This means that draining water from a single pool to the sewer system could potentially cause aquatic toxicity in the effluent of a medium-sized POTW.

Second, although POTWs break down pesticides to a varying degree, they are not designed to remove pesticides.⁴ Pesticides can potentially interfere with treatment plant operation, ability to recycle reclaimed water and biosolids, and compliance with NPDES permits. Some pesticides entering POTWs will pass through into water bodies downstream of the plants.

Furthermore, an exact determination of the impact of pool drainage on POTW effluent can not be made at this time, due to lack of data on the removal efficiency of PHMB at POTWs. EPA states in the Agency Response to Public Comments Submitted to the E-Docket on the PHMB Preliminary Risk Assessment (Response) dated November 22, 2005 that “no information on the efficiency of wastewater treatment technologies for PHMB was found” in the NRML Treatability Database for PHMB (US EPA/ORD/NRML) and that “predictive modeling (EPISUITE/EPIWIN, US EPA) could not be performed for PHMB.” Since no data is available, EPA should use the conservative assumption that all PHMB in the sewer system will pass-through POTWs without removal and be discharged into receiving waters. EPA should use this assumption as standard protocol in risk assessments in the absence of data to the contrary.

Instead, in the risk assessments, EPA assumed all PHMB is removed during wastewater treatment without providing technical data to support this conclusion. In addition, EPA states in the Response that “We are in the process of developing and validating various modeling programs, which will help us to ascertain that pesticides entering into U.S. water ways, as well as municipal waste treatment plants, are not at levels of concern.” Since EPA is in the “process of developing” modeling programs, how is it possible that EPA has already determined that pesticides entering surface water and municipal wastewater treatment plants “are not at levels of concern?” Tri-TAC is interested in the technical justification for this statement.

The brief environmental fate assessment prepared by EPA as part of the RED does not provide sufficient information to estimate the fate of PHMB in a POTW. It does suggest that PHMB may very well pass through typical treatment processes without much

⁴ Exact removal efficiencies of most pesticides in POTWs are not known, because EPA does not require this information to be submitted by pesticide registrants.

removal. While the environmental fate assessment shows that hydrolysis is an unlikely decomposition pathway,⁵ it does not assess biological degradation pathways. The high solubility and low octanol-water partition coefficient for PHMB suggest that the other typical removal mechanism—binding to wastewater biosolids—is unlikely. In order to fully assess potential impacts to POTWs from the use of PHMB, we recommend that studies be performed to determine the removal efficiency of PHMB at POTWs.

Finally, EPA states that “for certain use categories, such as indoor sanitizers or contained outdoor uses, such as swimming pools, the environmental exposure will be limited in most cases.” Therefore, EPA only requires “minimal toxicity data.” EPA also “does not currently undergo a full screening-level risk assessment” and considers these chemicals to fall under a “no effect” determination. As Tri-TAC has detailed above, when pools are drained, during overflows in rainy periods, and when filter backwash is discharged the resulting water enters either the sewer or storm drain systems. Therefore, a full data set on the impacts of PHMB on aquatic organisms is needed to evaluate the impacts to the environment from the use of this pesticide. EPA should require the registrants to submit acute and chronic aquatic toxicity test studies for estuarine/marine fish and invertebrates and chronic aquatic toxicity test results for freshwater and estuarine/marine fish and invertebrates. This data should be used to revise the risk assessments prior to reregistration.

In addition, EPA should evaluate PHMB effects on endangered species with a “full screening-level risk assessment” instead of determining “no effect” due to the low likelihood of exposure and low toxicity of PHMB. In the Risk Assessment, EPA concluded that PHMB is “moderately toxic to very highly acutely toxic to freshwater fish” and “highly to very highly toxic to freshwater invertebrates.” Since EPA waived the remaining aquatic toxicity testing, Tri-TAC is unclear on the basis for the “no effect” determination for listed species and critical habitat.

“Down the Drain” Assessment

Tri-TAC is concerned about the discharge of PHMB into sewers. Tri-TAC requests that EPA conduct an Aquatic Exposure, “Down the Drain Assessment”, similar to the analysis conducted for the “conventional” pesticide permethrin, to evaluate the potential impacts to aquatic organisms from the discharge of pools containing PHMB into the sewer system.

Tri-TAC has previously provided comments to EPA about the method used to translate POTW discharge concentrations from the Exposure and Fate Assessment Screening

⁵ The one hydrolysis study referenced in the risk assessment showed that PHMB is hydrolytically stable at pH 5, 7, and 9 at 25°C, and found that there was less than 10% degradation of PHMB in 30 days.

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 this pesticide. This result is significant because POTWs do not have the ability to regulate discharges of pesticides from domestic sources; however, POTWs are required to meet effluent aquatic toxicity standards in 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 PHMB discharged from pools, Tri-TAC requests that EPA require mitigation measures for PHMB prior to reregistration.

Publicly Owned Treatment Works

Another important consideration EPA should evaluate is the ability of POTWs to comply with the requirements in NPDES permits. In addition to the adverse environmental impacts, non-compliance with Clean Water Act requirements can be extremely costly for POTWs. Costs are incurred for identifying the source of the pollutants causing non-compliance, source control to reduce impacts of the pollutants, and construction, operation, and maintenance costs to upgrade POTWs with advanced treatment to remove pollutants that cannot be adequately reduced with source control. Also, when surface water bodies become impaired by pesticides, POTWs discharging to the water bodies can be impacted through additional requirements established as part of Total Maximum Daily Loads (TMDLs) set for the water bodies. In some instances POTWs are also subject to mandatory minimum penalties for NPDES exceedences and possible legal action. This is particularly important in areas such as the arid West, where POTWs discharge to effluent dominated water bodies, by providing essentially the only source of water to a surface water body during dry periods. The NPDES permits for these facilities do not include a stream dilution factor, so these POTWs often need to meet stringent NPDES permit limits at "end-of-the-pipe."

The POTWs' NPDES permits require that, "Wastes discharged shall not contain any substances in concentrations toxic to human, animal, plant, or aquatic life." They also require regular testing of effluent for aquatic toxicity. If an aquatic toxicity violation occurred as a result of discharge of a PHMB-containing wastewater, the POTW would have difficulty identifying the cause because EPA has not established an approved analytical method for this pesticide in wastewater.

In conclusion, POTWs need EPA's assistance to protect surface waters from contamination from pesticides. As previously discussed, POTWs are required by NPDES permits to meet aquatic toxicity standards but do not have the authority to regulate domestic sources of pesticides. Tri-TAC requests EPA conduct an Aquatic

Exposure, "Down the Drain" Assessment, similar to the analysis performed for permethrin, to evaluate the potential aquatic toxicity impacts from pool discharges containing PHMB into the sewers. In order to conduct this assessment, EPA must require aquatic toxicity data from the registrants to determine acute and chronic levels of concern. If the model shows that the levels of concern for aquatic organisms are exceeded from the use of PHMB, Tri-TAC requests that EPA require mitigation measures prior to reregistration. Requiring the necessary aquatic toxicity studies, using a conservative assumption for the removal of PHMB during wastewater treatment, and completing an assessment of the aquatic toxicity and NPDES permit compliance risks associated with sewer discharges is essential part of EPA's mandate to use sound science as the basis for its RED.

Contact Information

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

Sincerely,



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