

New York State Department of Environmental Conservation
Division of Solid & Hazardous Materials

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May 20, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Kimberly Fontaine-Goodwin
Operations Manager
E Paint Company
25 Research Road
East Falmouth, Massachusetts 02536

Dear Ms. Fontaine-Goodwin:

**Re: Registration of E Paint ZO (EPA Reg. No. 64684-4) and EP 2000 (EPA Reg. No. 64684-6), Both Contain the Active Ingredient Zinc Pyrithione (Zinc Omadine).
Chemical Code: 088002**

The New York State Department of Environmental Conservation (Department) has completed its review of the current product applications and data packages received from E Paint Company on June 4, 2004. The Department had previously denied registration of the above-referenced products (see Department letter dated September 15, 2003). At that time, the Department had resolved issues related to environmental fate and human health from use of the products. However, modeling of the amount of active ingredient released into the water column (release rate factor) continued to be unacceptable for the protection of aquatic species. Therefore, the Department's review of E Paint's new application was limited to nontarget organism impacts in fresh and saltwater environments.

E Paint Company submitted an application to register the pesticide products EP 2000 (EPA Reg. No. 64684-6) containing 4.7% zinc pyrithione, and EP ZO (EPA Reg. No. 64684-4) containing 4.8% zinc pyrithione, in New York State. These two products are antifouling paints intended for use on commercial and recreational watercraft. The Department has reviewed the intended use of EP 2000 and E Paint ZO on boat bottoms as a major change in labeled use pattern (MCL) for zinc pyrithione (zinc-2-pyridinethiol-1-oxide) in New York State.

The Department received the application and data package on June 4, 2004, and declared the application incomplete on July 23, 2004. Arch Chemicals, acting as the agent (active ingredient supplier) for E Paint, submitted three studies entitled:

“Sediment Toxicity Test with Zinc Pyrithione and Freshwater Amphipod, *Hyalella azteca*”

“Sediment Toxicity Test with Zinc Pyrithione and the Marine Amphipod, *Leptocheirus plumulosus*”

“Zinc Pyrithione: Influence on Growth and Growth Rate of the Marine Diatom, *Skeletonema costatum*”

The Department’s Bureau of Habitat reviewed these studies and declared the application and associated data packages to be complete for purposes of a technical review. The Department declared the application complete on September 23, 2004. In accordance with New York State ECL §33-0704, a registration decision date of February 18, 2005 was established.

Due to continued concerns for the protection of aquatic species. The Department granted a request from E Paint Company to waive the registration decision date for 90 days to May 20, 2005. The 90-day time frame allowed E Paint Company to submit references, documentation, or data from actual field studies which detail the concentration of zinc or copper pyrithione found in the environment from the use of antifoulant paints containing the active ingredient.

Arch Chemical Company provided two research papers in response to the Department’s request for actual field reports of environmental concentrations of the active ingredient in conjunction with its use as antifoulant paint:

“The Occurance, Fate and Effects of Selected Anti-fouling Paint Booster Biocides in UK Docks, Harbours, and Marinas. Kevin V. Thomas et. al. 2004 InSAFE Conference in Tokyo, Japan.” (No detection of zinc omadine reported from samples collected.)

“Determination of the antifouling agent zinc pyrithione in water samples by copper chelate formation and high-performance liquid chromatography-atmospheric pressure chemical ionization mass spectrometry,” J. of Chromatography A, 833 (1999), pp. 105-109, Kevin V. Thomas.

The Department also agreed to use the Marine Antifoulant Model-Predicted Environmental Concentration (MAM-PEC) model to determine the amount of active ingredient released into the water column and made available to aquatic organisms. The MAM-PEC model better simulates the impacts to the aquatic system from the use of antifoulants on boat surfaces than other models available to the Department.

The MAM-PEC model was utilized by the United States Environmental Protection Agency (USEPA) to revise the environmental modeling of zinc pyrithione as used in antifoulant paints (per Risk Assessment and Science Support Branch Memorandum dated April 22, 2004, re: “Revised Environmental Modeling for Zinc Omadine”). MAMPEC was commissioned by the Antifouling Working Group of the European Paint Makers Association (CEPE), and was sponsored by the European Commission. It was developed by B. Van Hattum of the Institute for Environmental Studies, Vrije Universiteit, The Netherlands, and, A.C. Bart and J.G. Boon of delft hydraulics.

The Department could not use the results of the USEPA's MAM-PEC modeling of environmental concentrations for zinc pyrithione, since the USEPA's model inputs were more representative of larger commercial craft and larger basins. E Paint Company seeks registration of two products (containing 4.7% and 4.8% zinc pyrithione) for use primarily by private recreational boat users that would use smaller pleasure boat marinas.

The Department requested Arch Chemical Company to calculate photodegradation half-lives based on New York State specific use sites. The Department provided raw data (chlorophyll (CHL), dissolved organic carbon (DOC) and suspended sediment (SUSED)) from six sites on Long Island to Arch Chemical Company to run through the USEPA Exposure Analysis Modeling System (EXAMS) model to calculate the photolysis half-life for each site. Other relevant EXAMS parameters are the water body depth (6 ft. = 1.83 meters), the latitude (42°N - Elmira, NY), cloud cover (50%), relative humidity (50%), elevation (0) and air mass type (Maritime). The following photolysis half-lives were provided to the Department by Arch Chemical Company:

Location	CHL	DOC	SUSED	Photolysis T (hr.)	Photolysis T (hr.)
N. Shore #1	0.0132	2.3	52.0	8.0	4.8
#2	0.0037	1.5	7.7	2.4	1.4
#3	0.0001	1.1	1.0	1.2	0.71
S. Shore #1	0.070	6.1	52.0	12.9	7.7
#2	0.0090	2.43	11	3.7	2.2
#3	0.0010	0.88	1.0	1.1	0.67

The MAM-PEC model was run using the New York State specific parameters and parameters for small pleasure craft docking facilities. The MAMPEC exposure scenario most representative of the types of areas where toxicity was expected to occur was the Poorly Flushed Marina which best represents poorly flushed areas like the Great South Bay on Long Island.

Modeling Parameters:

MAMPEC is a fairly complex multi-compartment model which allowed the Department to conduct a more refined assessment of zinc pyrithione by weighting its various fate pathways more realistically. It consists primarily of three main modules, Environment, Compound, and Emission, that come pre-loaded with default scenarios/parameters and allows modification of the defaults or construction of new environments and entry of new chemicals.

The Compound module input parameters in the default scenario were corrected to reflect USEPA validated study results submitted to this Department.

The relevant water column parameters in the Environment module, such as silt concentration, particulate and dissolved organic carbon, made very small differences in the water column concentration of zinc pyrithione. Therefore, these parameters were left as set in the default scenario. The depth of the marina in the model was adjusted to 2 meters to correspond to the calculated photolysis constants provided by Arch Chemical Company.

The Emission module was used to evaluate a range of zinc pyrithione loading rates. Values of 10%, 20%, and 30% treatment of boats with E Paint products (EP 2000 & E Paint-ZO) moored in the marina were plugged into the MAM-PEC model with the environment and compound modules set to model the poorly flushed pleasure craft marina.

The Department believed there were two factors that were not addressed by the MAMPEC model. The first being transchelation of zinc pyrithione to copper pyrithione in the water column and the second being the effect of the shaded areas under the boats and docks that may reduce the photolytic degradation rate of zinc pyrithione and/or copper pyrithione. The Department made adjustments to the photolysis half-life in the MAM-PEC model to better predict water column concentration of the active ingredient.

The standard small boat marina was assumed to be 60% shaded by boats and docks. Shaded areas were determined to have a photolysis rate half that of open areas. The median June photolysis rate of 2.2 hours was adjusted to 3.2 hours to accommodate increased shade.

The transchelation of zinc pyrithione to copper pyrithione was reviewed in the Arch Treatment Products Report entitled "Aquatic Fate and Toxic Effects of Zinc Omadine and Copper Omadine Review and Preliminary Risk Assessment." The report describes a seawater die away study which demonstrates that after 24 hours, 50% of the zinc pyrithione transchelates to copper pyrithione, in the presence of copper. Copper is widely used as antifoulant and is typically found in marina water. The photolytic half-life of copper pyrithione is stated as being nearly twice that of zinc pyrithione. It is also reported that copper pyrithione and zinc pyrithione have similar toxicity to aquatic organisms. To account for the toxicity resulting from introducing zinc pyrithione into a copper rich environment, the shade adjusted photolytic half-life was doubled to 6.4 hours. Therefore, the MAM-PEC modeling was conducted using the high end photolysis rate submitted by Arch for the south shore of Long Island, or 7.7 hours to address Department concerns.

Three runs of the above poorly flushed marina scenario were made using increased use rates (10%, 20%, and 30%) of the E Paint zinc pyrithione products. Under the modeled conditions, if 30% of the boats in a marina are painted with zinc pyrithione based products, water column concentrations of 2.2 parts per billion (ppb) would result. Toxicity end points are somewhat higher than the predicted water concentration. The fathead minnow LC_{50} is 2.68 ppb while the LC_{50} and EC_{50} values are all around 3 ppb for other freshwater organisms. LC_{50} and EC_{50} values range from 4.7 ppb for mysid shrimp up to 400 ppb for sheepshead minnow in marine waters. Therefore, if use rates do not exceed 30% in any given area, adverse effects to aquatic life are not likely to occur. Arch Chemical Company has provided documentation that zinc pyrithione antifoulant products currently capture 15% market share for the residential/pleasure craft user.

Summary:

When used as labeled, E Paint ZO (EPA Reg. No. 64684-4) and EP 2000 (EPA Reg. No. 64684-6) will not have adverse effects on aquatic organisms. The USEPA is continuing to work on the Reregistration Eligibility Decision (RED) Memorandum for use of zinc pyrithione in antifoulant paint products. The USEPA is providing registrants time-limited conditional registrations for antifoulants containing zinc pyrithione until September 30, 2006.

Therefore, the Department will register your products until September 30, 2006. Prior to reregistration of your products, your Company will be required to submit USEPA documentation (such as the RED) along with corrected product labeling which complies with any requirements of the RED. The Department may also reevaluate its determination of impacts to human health based on any new data provided in the RED specific to dermal contact by the product user.

Enclosed for your record is the Certificate of Registration and a copy of the stamped accepted labeling for E Paint ZO (EPA Reg. No. 64684-4) and EP 2000 (EPA Reg. No. 64684-6). Please note that a proposal by E Paint Company or any other registrant, to register a product that contains zinc pyrithione for antifoulant use or any other labeled uses that are likely to increase the potential for significant impact to humans, nontarget organisms, or the environment, would constitute a major change in labeled (MCL) use pattern. Such an application must be accompanied by a new application fee and meet the requirements listed in Appendix 1.B. of "New York State Pesticide Product Registration Procedures" (August 1996). Such information, as well as forms, can be accessed at our website as listed in our letterhead.

Please be aware that any unregistered product may **not** be sold, offered for sale, distributed, or used in New York State.

If you have any questions on this matter, please contact our Pesticide Product Registration Section, at (518) 402-8768.

Sincerely,

Maureen P. Serafini
Director
Bureau of Pesticides Management

Enclosures

cc: Garrett B Schifilliti, Arch Chemicals, Inc.
N. Kim/D. Luttinger - NYS Dept. of Health
R. Zimmerman/R. Mungari - NYS Dept. of Ag. & Markets
W. Smith - Cornell University, PMEP