



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

3/29/2022

SUBJECT: Response to Public Comments on the Chlorothalonil Draft Risk Assessment for antimicrobial uses.

PC Code(s): 081901	DP Barcode(s)/No(s): 463821
Decision No.: 579174	Docket No(s): EPA-HQ-OPP-2011-0840
Petition No(s): NA	Regulatory Action: RTC
Risk Assessment Type: Draft	Case No(s): 0097
TXR No.: NA	CAS No(s): 1897-45-6

From: James Breithaupt, Agronomist *James Breithaupt*
Blossom Catacutan, Biologist *Blossom Catacutan*
Timothy C. Dole, CIH, Industrial Hygienist *Timothy C. Dole*
Jorge G. Muñoz Ortiz, Ph.D., DABT, Toxicologist *Jorge G. Muñoz Ortiz*
Risk Assessment Branch 1 and 2
Antimicrobials Division (7510P)

Thru: Elizabeth Donovan, Branch Chief
Judy Facey, Ph.D., Risk Assessment Process Leader
Tim McMahon, Ph.D., Senior Science Advisor *Tim McMahon*
Risk Assessment Branch 2
Antimicrobials Division (7510P)

To: Peter Bergquist, Chemical Review Manager
Matthew Manupella, Team Leader
Rose Kyprianou, Branch Chief
Reevaluation Branch
Antimicrobials Division (7510P)

Introduction

The Agency completed a Registration Review Draft Risk Assessment (DRA, U.S. EPA, 2021) for the antimicrobial uses for the active ingredient (a.i.) Chlorothalonil (PC Code 081901) in 2021 that has been posted on www.regulations.gov in docket number EPA-HQ-OPP-2011-0840. During the public comment period the Agency received comments from the California

Stormwater Quality Association (CASQA), Koppers Performance Chemicals (KPC), and IBC Manufacturing Company (IBC). The comments submitted on the antimicrobial use draft risk assessment and the Agency's responses to the science comments specific to antimicrobial uses are provided below.

Comments Submitted by California Stormwater Quality Association (CASQA)

CASQA Comment: Significant risk to aquatic life; Mitigation is Needed: The commenter states that while EPA's risk calculations are based on 100% leaching of chlorothalonil from the treated surface, many urban and suburban watersheds include hundreds or even thousands of residential and commercial buildings. Based on EPA's calculations, if even a small fraction of those buildings were painted with paint containing chlorothalonil in a given year, and if even a fraction of the chlorothalonil contained in the paint leaches to a surface water body, freshwater life could be at risk. These results indicated a clear need for mitigation to protect aquatic life from legal uses of chlorothalonil within urban watersheds.

Agency Response: The screening-level modeling does not differentiate between urban and rural structures being painted with coatings that contain chlorothalonil. The modeling already assumes that painted buildings are surrounded by impervious surfaces, resulting in direct runoff to the nearest waterbody. As a result, the modeling already accounts for the impervious surfaces in urban areas. Furthermore, the modeling uses conservative assumptions, and various factors would contribute to a much lower rate of exposure than the current model shows. 1) 100% of chlorothalonil would not leach from a freshly-painted house during a single rainfall event. 2) Not all houses in a single watershed are painted simultaneously. 3) It is not realistic that 100% of a house would get wet under a typical rainfall event because of prevailing winds that blow the rainfall and expose certain walls of the house primarily. 4) Not all houses are surrounded by impervious surfaces. The amount of chlorothalonil that reaches a waterbody would be reduced by sorption to soil/sediment.

Comments Submitted by IBC Manufacturing Company

IBC Comment: Human Health Exposure: IBC agrees that, with the exception of occupational handler exposures anticipated when chlorothalonil is used to preserve materials, all chlorothalonil antimicrobial uses are not of concern to humans. The inhalation MOE for occupational handlers of 1.8 for open pouring of powder at the application rate of 9,800 ppm for exterior paint is of concern because it is less than the LOC of 3. However, with the addition of a PF 10 respirator which reduces inhalation exposure by 90%, the MOE for this use is acceptable.

Agency Response: The labels do not currently require respirators, so the MOE was calculated without respirators. If the labels were amended to include PF-10 respirators, the MOE could be recalculated.

IBC Comment: Ecological Exposure from Exterior paints and coatings use: The most sensitive species/exposure scenario is freshwater invertebrates exposed via chronic exposures. The commenter states that this is incongruent with the exposure scenario where a single bolus load is assumed in association with a chronic exposure and that no partitioning into the sediment compartment nor degradation over time is considered. The commenter believed that this is a very conservative assumption, and the Agency should discount the importance of this species/exposure scenario combination because of the conservatism of the calculations used in the exposure analysis.

Agency Response: The typical durations for chronic and sub-chronic studies (21 days for invertebrates and 28 to 70 days for fish) do not define the true exposure duration needed to elicit the observed responses. These studies are designed to understand the potential for sublethal effects from exposure to a chemical but are not designed to determine how many exposures are needed to elicit a sublethal effect. A pesticide may exert effects at critical periods of the life cycle or early life stage studies; therefore, long-term exposure may not be necessary to elicit the effect observed in the studies. The screening-level risk assessment uses the single-day maximum estimated environmental concentration (EEC) as a conservative approach.

Comments Submitted by Koppers Performance Chemicals, Inc. (KPC)

KPC Comment: Residential Post Application Exposure to Pressure Treated Wood: KPC states that there are more than two products with pressure treatment uses. In addition to the two products (EPA Reg. Nos. 1022-584 and 6836-433) mentioned on page 13 of the DRA (U.S. EPA, 2021), the following are just a few other registrations: EPA Reg. Nos. 3008-125, 62190-36, and 72304-1.

Agency Response: The Agency concurs that there are other products such as EPA Reg. Nos. 3008-125, 62190-36, and 72304-1 that have instructions for incorporating chlorothalonil into the pressure treatment solution.

KPC Comment: The use rate of 2000 ppm a.i. in the final treatment solution is exaggerated: KPC states that the use rate of 2,000 ppm a.i. in the final treatment solution is exaggerated. According to KPC, Section 2.4.2 of the DRA (U.S. EPA, 2021) correctly states that the two registrations (Reg. Nos. 1022-584 and 6836-433) have use rates of 0.2 to 0.4 gallons of product per 100 gallons of pressure treating solution. However, the treating solution would not contain 0.2% a.i. (2000 ppm a.i.). The correct concentration is 0.0808% - 0.1616% a.i. (808 - 1,616 ppm).

Agency Response: The application rate of 2000 ppm a.i. for pressure treatment application rates using EPA Reg Nos. 1022-584 and 6836-433 is based on the product application rate of 0.4 gallons of product in 100 gallons of pressure treating solution. It was assumed that the products, which have 40.4% chlorothalonil, contains 4.17 lbs chlorothalonil per gallon, based on three other products (1448-372, 53883-192 and 72304-1) that contain 40.4 % chlorothalonil. It was also assumed that the treatment solution was water based with a density of 8.35 lb per gallon. Given these two assumptions, 0.4 gallons of product (1.67 lbs chlorothalonil a.i.) yields 2,000 ppm a.i. when added to 100 gallons of water as shown in the calculation below.

$$\text{Treatment Solution Concentration (2000 ppm a.i.)} = \frac{1.67 \text{ lbs chlorothalonil a.i.}}{100\text{-gal treatment solution} \times 8.35 \text{ lbs/gal}} \times 1,000,000 \text{ ppm}$$

KPC Comment: The label for EPA Reg. No. 3008-125 has a lower application rate of 0.02 to 0.06 gallons of product per 100 gallons of pressure treating solution, resulting in 0.008% to 0.024% a.i. (80.8 - 242.4 ppm).

Agency Response: The application rate is 100 to 350 ppm a.i. for EPA Reg 3008-125, when 0.02 to 0.06 gallons of product are added to 100 gallons of treatment solution. The product label indicates that the product contains 4.17 lbs chlorothalonil per gallon. If it is also assumed that the treatment solution was water based, the addition of 0.02 gallons of product (0.083 lbs chlorothalonil) yields 100 ppm when added to 100 gallons of water. The addition of 0.06 gallons of product (0.25 lbs chlorothalonil) yields 300 ppm when added to 100 gallons of water.

KPC Comment: The leaching study (MRID 49667201) tested treating solutions containing 150, 200 and 300 ppm a.i. and that the wood wipe study (MRID 49667202) used solutions that contained 150 ppm a.i.

Agency Response: The Agency concurs that the leaching study (MRID 49667201) tested treating solutions containing 150, 200 and 300 ppm a.i. and that the wood wipe study (MRID 49667202) used solutions that contained 150 ppm a.i. Since these studies were used to assess environmental and human health risks of pressure treated wood, there is uncertainty regarding these risks if the wood is treated using application rates that exceed 300 ppm. Four products (EPA Reg Nos 1022-584, 6836-433 and 62190-36) have an application rate of 2,000 ppm and one product (EPA Reg No. 72304-1) has an application rate of 5,000 ppm.

KPC Comment: Reference to 2009 Lebow study, Pressure Treatment with a Water-based Chlorothalonil Formulation: KPC states that page 14 of the DRA and other sections reference Lebow (2009) that used a 1% chlorothalonil solution to obtain 0.3 to 0.4 pounds per cubic foot (pcf). KPC states that Lebow (2009) was an experimental research and development study, and the purpose of Lebow (2009) was not for efficacy as the DRA (U.S. EPA, 2021) suggests. It was conducted to evaluate the ability of a waterborne chlorothalonil formulation to penetrate into

Southern Pine lumber. The US Forest Service chose a target retention of 4.8 kg/m³ (0.3 pcf) using a formulation containing 1% chlorothalonil. This retention has never been approved by any wood preservation industry associations, nor has it been used commercially. It does not represent application rates on the registered labels, or the concentrations currently used in the wood preservative market.

Agency Response: The Agency concurs that the purpose of Lebow (2009) was to evaluate the penetration of chlorothalonil into wood and that it does not represent current chlorothalonil labels. These rates were not quantitatively used in the risk assessment, but they were used to estimate what retention rate would be obtained using the treatment solution concentration listed on the labels. For example, EPA Reg No. 1022-584 only lists the treatment solution concentration of 0.2% a.i. It does not list the retention rate. The target retention for this product was estimated to be 0.06 to 0.08 pcf (*i.e.*, five times less) based on Lebow (2009) where retentions of 0.3 to 0.4 pcf were obtained following pressure treatment using a solution containing 1 percent a.i.

References:

- Lebow, 2009. Pressure Treatment with a Water-based Chlorothalonil Formulation, Lebow, S., Lebow, P., Clausen, C., Halverson, S., US Forest Service, Forest Products Laboratory and Burley, J., Sostram Corporation. In Proceedings: One Hundred Fifth Annual Meeting of the American Wood Protection Association, San Antonio, Texas, April 19-21, 2009 Volume 105.
- U.S. EPA, 2021. Registration Review Draft Risk Assessment (DRA) for the Antimicrobial Uses of Chlorothalonil. D459727 April 9, 2021.