



AmericanCoatings
ASSOCIATIONSM

Anna Romanovsky
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW,
Washington, DC 20460-0001

July 27, 2022

Re: Propiconazole, Proposed Interim Decision, EPA-HQ-OPP-2015-0459
Submitted via www.regulations.gov

Dear Ms. Romanovsky:

The American Coatings Association (ACA) appreciates the opportunity to submit comment on EPA's Proposed Interim Decision (PID) for propiconazole. ACA is a voluntary, non-profit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents manufacturers of paints, coatings, sealants, adhesives, raw materials suppliers, distributors, and technical professionals. ACA's membership represents over 90 percent of the total domestic production of paints and coatings. ACA and its members are committed to bringing safe products to market with minimal environmental impacts, based on accurate assessment of risks associated with products. ACA and its members respectfully submit the following comment:

I. Introduction

EPA published its Proposed Interim Decision (PID) in March 2022 as part of its registration review of propiconazole. In the PID, EPA proposes a reduction in use rate to 1.12% active ingredient in the final formulated product, based on EPA's DRA (draft risk assessment), published on December 1, 2020. ACA had filed comment in response to the DRA, noting concerns with data sets used to assess exposure of workers formulating paint, professional painters and consumers applying paint with propiconazole added as a material preservative.

ACA's comment included three attachments as appendices detailing challenges in identifying viable substitutes for biocides in paint formulation, environmental costs of substitution, the need for effective preservatives and challenges related formulating paints with biocides. ACA hopes that this information can be more fully considered within the context of EPA's PID.

EPA's PID adopts and refers to EPA's response to comments on the DRA, dated March 21, 2022.

ACA appreciates EPA's willingness to respond to stakeholder comment. In this comment, ACA would like to address two issues raised in EPA's PID and Response to Comments. ACA submits additional information related to EPA's identification of alternatives. ACA also suggests that EPA factor into its exposure assessment workplace PPE and respiratory protection whose use is ubiquitous with professional painters.

I. Benefits analysis

EPA considers the feasibility of alternatives in the PID at *Appendix E: Benefits Assessment of Antimicrobial Uses of Propiconazole*. EPA cites to an internal presentation by the ACA to support its conclusion:

Available (propiconazole substitute) chemicals primarily include IPBC, OIT, DCOIT, zinc pyrithione, and PCMC. While there are other identified alternatives listed in Table 1, they are less viable compared to those included in this discussion.

Each of these biocides presents challenges related to formulation, requiring reformulation of paint products. These are not ready "drop in" substitutes. Reformulation is typically a costly and time consuming endeavor, similar to developing a new product, requiring research and development, testing and approval by downstream buyers in some cases. The identified alternatives present the following technical challenges:

- IPBC has good stability across acidic and neutral pH ranges, but can hydrolyze at higher alkaline pH ranges. The 2016 Kline Report, cited by EPA in support of IPBC as an alternative, overestimates suitability of IPBC across a pH range of 4 to 10.86.
- EPA notes that IPBC can be used in conjunction with other biocides. This is accurate, and it emphasizes the importance of preserving a selection of biocides providing versatility in preservation characteristics. For example, carbendazim and diuron can be used in conjunction with IPBC, but these may be restricted or eliminated from paint formulation by ongoing registration reviews.
- EPA notes that like OIT, DCOIT is classified as a skin sensitizer with low concentration limit, which could also prove challenging for users, but when utilized, it offers stability under high temperatures. ACA recommends considering overall product characteristics and stability. OIT has good temperature stability, but it can leach out of the film at much higher amounts than propiconazole or some other dry-film preservatives. For an in-depth discussion of varying characteristics of biocides, see *Extending the Life of Dry Film Coatings by Selecting the Right Preservative Systems*.¹
- EPA cites an ACA internal presentation, noting that zinc pyrithione offers low volatility and high temperature stability and can work with BIT or MIT, as a viable propiconazole substitute. ACA further notes that zinc pyrithione can cause discoloration of the paint (typically darkening) and the combination of zinc pyrithione with BIT or MIT is meant to

¹ *Extending the Life of Dry Film Coatings by Selecting the Right Preservative Systems* (October 2019), available online at: https://www.coatingsworld.com/issues/2019-10-01/view_technical-papers/extending-the-life-of-dry-film-coatings-by-selecting-the-right-preservative-systems/

improve the wet-state efficacy (in-can preservation) and not the dry-film efficacy.

- EPA notes that the 2016 Kline Report identifies PCMC as a substitute. The Kline Report states that PCMC offers preservation against a wide range of bacteria, yeast, and mold fungi. ACA is not aware of paint products that use PCMC for dry-film protection against mildew in paints, although the label permits this use. ACA is unaware of a zero-VOC formulations of PCMC suitable for use with modern zero-VOC, waterborne architectural paints.

Selection of alternatives involves a complicated analysis of efficacy, pH stability, wet stage activity, leaching, evaporation, discoloration, ability to incorporate into formulation, temperature considerations and other factors. ACA requests that EPA consider unique properties of biocides and the challenges presented when reformulating. Further, EPA should be aware of the broader impact of its registration review process in eliminating available alternatives. ACA also requests that EPA evaluate benefits information ACA previously submitted as part of EPA's benefits analysis in the PID. ACA submitted this information in Attachments A-C of ACA's comment on the DRA.

ACA further requests that EPA consider information related to efficacy previously submitted in an internal presentation to EPA. Noting that paint products are carefully formulated to maximize efficacy, often with trace amounts of biocides, please consider the following costs associated with compromising efficacy by substitution of biocides:

- An estimated 42 million housing units in the United States may have mold.
- Indoor mold is prevalent in about 5-10% of houses in cold climates and 10-30% of houses in warm climates.
- Professional mold remediation costs about \$500-\$6,000 per project and can be in the tens of thousands for severe cases.
- Dampness and mold related infections cost the U.S. economy about 5.6 billion per year, with costs from asthma morbidity estimated at \$15.1 billion per year and asthma mortality estimated at \$1.7 billion per year.
- Of the 21.8 million asthma sufferers in the U.S., about \$4.6 million, about 21%, are estimated as attributed to residential dampness and mold.
- Dampness and mold are estimated to cause an increase of 30%-50% in the rate of respiratory illness.

For complete citations see Attachment A, including additional references. This information was also previously submitted to EPA as part of an ACA presentation. ACA requests that EPA consider this information in the benefits analysis as part of a broader analysis of overall benefits in relation to estimated risk, considering overall confidence in conclusions, and proposed mitigation measures.

II. EPA must consider workplace practices in the Draft Risk Assessment

As noted in ACA's comment on the draft risk assessment, ACA strongly recommends that EPA consider standard workplace practices such as respiratory protection and other PPE when evaluating workplace risk by profession painters using airless sprayers. In its response to comment, EPA states:

Preserved paints are treated articles that are not registered as pesticide products. Therefore, there are no labels to communicate the need for PPE. (EPA Response to Comment, page 13)

In practice, painters must comply with existing law that require use of respiratory protection and other PPE for spray application of paint. Manufacturers communicate related information to painters via Safety Data Sheets. EPA has broad discretion to identify relevant information for a DRA. EPA seems concerned that information communicated to painters does not warn specifically for risks associated with biocides. To assess that risk, EPA must realistically consider all factors affecting exposure, including current practices.

FIFRA and implementing regulations do not restrict EPA's consideration of PPE and ventilation when considering safety during use or formulation of a treated article. Standard practices in risk assessment would weigh in favor of EPA considering all conditions relevant to exposure, including standard workplace practices. Here, EPA has assumed authority to evaluate safety related to biocide exposure from a treated article, but then argues that it will not consider a full set of considerations related to that exposure scenario because it has not mandated a labeling program specific to biocides in paint.

OSHA has an existing respiratory protection standard, requiring respiratory protection when spray applying paint. OSHA's requirement includes processes for respirator selection and use. Under 29 CFR 1910.134, an employer must maintain:

- Procedures for selection of PPE.
- Medical evaluations of employees using respirators.
- Fit and tight testing procedures
- Procedures for proper respirator use.
- Procedures for regular respirator maintenance.
- Employee training in hazards and use of respirators.
- Procedures for regularly evaluating effectiveness of the program.

Industrial hygienists develop standard references and practices conveyed to painters on a Safety Data Sheet, including hazard identification under the OSHA Hazard Communication Standard at 29 CFR 1910.1200. The employer ultimately has the responsibility to implement protective measures using the manufacturers' information and any other references.²

The International Union of Painters and Allied Trades (IUPAT) confirms that respiratory protection, gloves and other protective clothing are universally used by professional painters, implementing the OSHA standard. The IUPAT notes its standard training for professional painters covers identification and selection of PPE and respirators and other relevant topics, including:

- OSHA 10/30 training

² Section 5 of the *Occupational Safety and Health Act*, that is the "general duty clause:"

"Each employer . . . shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."

- Respirator training course and fit testing, both quantitative and qualitative requirements
- Extensive Course in reading and understanding the Safety Data Sheet (SDS) and Product Data Sheet (PDS)
- hazard communication
- hazardous waste
- proper selection and use of PPE
- course Understanding the hierarchy of controls and why PPE needs to be the lowest in the hierarchy for protection.

EPA's concern here is that respiratory protection and PPE are not selected pursuant to a label identifying risk of exposure to biocides in a paint. For the purpose of assessing risk, this is irrelevant. *EPA's Framework for Human Health Risk Assessment to Inform Decision Making*³ provides as a general principle:

Risk assessments should be based on exposure scenarios that are consistent with the purpose and context. As appropriate, they should include consideration of susceptible population groups and life stages.

Another general principle requires, "A risk assessment should be fit for its intended purpose." Susceptible populations include profession painters and the complete exposure scenario that could cause risk. *EPA's Guidelines for Human Exposure Assessments*⁴ includes similar principles as foundational to a risk assessment.

Exclusion of factors affecting exposure is not supported by FIFRA. If EPA is to evaluate exposure at all, it must do so accurately, not by excluding critical elements such as common workplace practices including respiratory protection and PPE. ACA recommends suspending evaluation of risk mitigation strategies so EPA can incorporate related information ACA submitted in comment to the DRA and / or gather additional information.

III. Volumes of paint handled by residential spray applicators are conservative estimates.

ACA notes that volumes of paint handled by residential applicators are conservative estimates, while noting this is probably by design or possibly due to outdated information. ACA previously suggested that a residential spray painter (that is, *not* a professional painter), might handle about 5 gallons of paint per day. This is based on paint products with coverage of 250-400 square feet / gallon. EPA's estimate relies on an assumption of coverage of 200 square feet / gallon, resulting in 15 gallons of paint used per day.⁵ ACA would welcome the opportunity to update and revise data sets EPA uses for registration review related to paint application and paint formulation.

³ . *EPA's Framework for Human Health Risk Assessment to Inform Decision Making* (April 2014), See p. 16 for general risk assessment principles, available at: <https://www.epa.gov/sites/default/files/2014-12/documents/hhra-framework-final-2014.pdf>.

⁴ *EPA's Guidelines for Human Exposure Assessments* (October 2019), available at: https://www.epa.gov/sites/default/files/2020-01/documents/guidelines_for_human_exposure_assessment_final2019.pdf.

⁵ EPA Response to Comments on the Propiconazole DRA (March 21, 2022), page. 12.

IV. Conclusion

ACA appreciates the opportunity to submit comment on EPA's PID for propiconazole. Please consider the following suggestions:

- ACA requests that EPA consider unique properties of biocides and the challenges presented when reformulating, particularly related to reformulation of paint products using alternatives identified in the PID.
- EPA should be aware of the broader impact of its registration review process in eliminating available alternatives, often identified as viable alternatives in a PID, but scheduled for restriction through the ongoing registration review process or another PID.
- ACA also requests that EPA evaluate benefits information ACA previously submitted as part of EPA's benefits analysis in the PID. ACA submitted this information in Attachments A-C of ACA's comment on the DRA.
- ACA recommends that EPA broaden the scope of its benefits analysis to consider effect on human and health and the environment from restriction of propiconazole, including costs associated with those effects and costs associated with reformulating. ACA submitted related information in an internal presentation, in Attachment A-C of ACA's comment on the DRA and in Attachment A to this comment.
- ACA strongly recommends that EPA consider standard workplace practices such as respiratory protection and other PPE in the workplace when evaluating workplace risk by profession painters using airless sprayers.
- ACA recommends initiating a joint project with EPA to update default data related exposure to biocides from paint.

Thank you for considering these comments. We look forward to working with EPA to develop an accurate understanding of risks association with propiconazole in paint products and appropriate mitigation strategies. ACA hopes to meet with EPA to discuss these issues further. In the meantime, please feel free to contact me if I can provide any additional information.

Sincerely,

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Attachment A – Cost of Mold Contamination

Some facts and figures about mold issues in the US

Potential Property & Financial Impacts

- “The prevalence of indoor mold has been 5–10% in cold climate and **10–30%** in moderate and warm climates.”
 - “Residential Dampness and Molds and the Risk of Developing Asthma: A Systematic Review and Meta Analysis,” Quarstein, R., et al, PLoS One. 2012; 7(11): e47526. doi: 10.1371/journal.pone.0047526
- Thus, up to **42 million** housing units in the US may have mold
 - <https://www.statista.com/statistics/740767/number-of-housing-units-in-the-united-states>
- Professional mold remediation costs about **\$500 – \$ 6000** per project
 - in severe cases tens of thousands
 - Rt <https://homeguide.com/costs/mold-removal-cost>
- Dampness & mold-related infections cost the US economy **~\$5.6 Bn / year**; asthma morbidity **~\$15.1 Bn**; and asthma mortality **~\$1.7 Bn**
 - Mudarri, J. Environ Public Health, 2016;2016:2386595

<https://www.cdc.gov/nceh/publications/books/housing/cha05.htm>

https://www.fema.gov/pdf/rebuild/recover/fema_mold_brochure_english.pdf

<https://www.epa.gov/mold/brief-guide-mold-moisture-and-your-home>

Potential Human Health Issues

- **93%** of Chronic sinusitis infections have been attributable to mold
 - “The Diagnosis and Incidence of Allergic Fungal Sinusitis,” Ponikvar, J.U., et al, Mayo Clinic Proceedings, Volume 74, Issue 9 (1999), pages 877-884
- Of the 21.8 million asthma sufferers in the US, **~4.6 million** (i.e., 21%) are estimated to be attributable to dampness & mold exposure in the home
 - Mudarri, D. & Fisk, W. L. (2007). “Public health and economic impact of dampness and mold.” *Indoor Air*, 17(3), 226-235. doi: 10.1111/j.1600-0668.2007.00474.x
- Dampness & mold are estimated to cause an increase of **30-50%** in the rate of respiratory illness
 - *ibid*