July 10, 2019

Comments from Academics, Scientists and Clinicians on the Draft Updated Risk Characterization for Occupational Inhalation of C. I. Pigment Violet 29

Submitted online via Regulations.gov to docket EPA-HQ-OPPT-2018-0604

These comments are submitted on behalf of the undersigned academics, scientists, and clinicians. We declare collectively that we have no direct or indirect financial or fiduciary interest in any chemical or product that is the subject of these comments. The co-signers’ institutional affiliations are included for identification purposes only and do not imply institutional endorsement or support unless indicated otherwise.

We appreciate the opportunity to provide written comments on the updated risk characterization for occupational inhalation for Pigment Violet 29,¹ issued under EPA’s Toxic Substances Control Act (TSCA), as amended by the Frank R. Launtenberg Chemical Safety for the 21st Century Act (“amended TSCA”). The law requires that EPA make determinations about chemical risks based on adequate information and the best available science.² Unfortunately, EPA’s original risk evaluation and subsequent analyses on Pigment Violet 29, including the current updated occupational risk characterization, fall woefully short on these mandates.

We previously commented in January and May of 2019 that EPA does not possess adequate data to support its determination that Pigment Violet 29 does not pose an unreasonable risk. Additionally, we found that EPA’s risk evaluation was insufficient because of quality deficiencies and critical data gaps.³,⁴ Data gaps remain a major problem in EPA’s June 2019 inhalation analysis for Pigment Violet 29 which proposed two approaches to characterize occupational risk; both inappropriately chose lung overload as the relevant toxicity endpoint.⁵

**EPA assumes that Pigment Violet 29 is non-toxic and not absorbed via inhalation without providing adequate empirical data to support such assumptions.**

Although EPA expects inhalation to be a major route of exposure for workers,⁶ EPA acknowledges it has no available data on the inhalation route for Pigment Violet 29, for either absorption or hazard:

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² 15 USC §2601 (b)(1) and 15 USC §2625 (h)


“Absorption was assumed based on physical chemical properties. No data were identified on the metabolism of PV29. No acceptable acute or chronic inhalation studies available for PV29.”  

EPA’s new inhalation analyses rely on numerous assumptions that do not have any supporting empirical data, including that Pigment Violet 29 is:

- Poorly respirable,
- Poorly soluble/ having low solubility,
- Poorly absorbed,
- Not metabolized, and
- Not inherently toxic

But other authoritative bodies have called these assumptions into question. The European Chemicals Agency (ECHA) recently released data stating that Pigment Violet 29 presents persistence, bioaccumulation and toxicity concerns, and calling for further study.

With regard to respirability, ECHA indicates that Pigment Violet 29 has a “high potential for bioaccumulation in air-breathers. Based on this observation [Pigment Violet 29] may accumulate in terrestrial organisms and in mammals.”

ECHA’s findings also counter EPAs claim regarding the insolubility of Pigment Violet 29, calling the solubility “questionable.” Additionally, ECHA’s update document indicates toxicity concerns around Pigment Violet 29 due to its structural similarity to polycyclic aromatic hydrocarbons, of which many are carcinogenic.

If any of EPA’s assumptions about Pigment Violet 29’s toxicity, exposure, or physical-chemical characteristics is not valid, then both lung overload analyses are also not valid. Because of these major data gaps, EPA’s new occupational inhalation analysis fails to demonstrate that Pigment Violet is not risky.

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10 Id. Page 13.
11 Id. Page 13.
We therefore recommend that EPA obtain adequate data on Pigment Violet, complete a new risk evaluation, and ensure the protection of workers, communities, and other populations facing health threats from Pigment Violet 29.

We appreciate the opportunity to provide public input. Please do not hesitate to contact us with any questions regarding these comments.

Sincerely,

Swati Rayasam, MSc
Science Associate, Program on Reproductive Health and the Environment
Department of Obstetrics, Gynecology and Reproductive Sciences
University of California, San Francisco

Veena Singla, PhD
Associate Director, Program on Reproductive Health and the Environment
Department of Obstetrics, Gynecology and Reproductive Sciences
University of California, San Francisco

Tracey Woodruff, PhD, MPH
Professor and Director, Program on Reproductive Health and the Environment
Department of Obstetrics, Gynecology and Reproductive Sciences
University of California, San Francisco

Phil Brown, PhD
University Distinguished Professor of Sociology and Health Science
Northeastern University

Courtney Cooper, BS
Research Assistant, Program on Reproductive Health and the Environment
Department of Obstetrics, Gynecology and Reproductive Sciences
University of California, San Francisco

Mary Gant, MSc
Policy Analyst (retired)
National Institute of Environmental Health Sciences

Steven Gilbert, PhD, DABT
Affiliate Professor, Environmental and Occupational Health Sciences
University of Washington, Seattle

Robert M. Gould, MD
Associate Adjunct Professor, Department of Obstetrics, Gynecology and Reproductive Sciences,
University of California, San Francisco School of Medicine
Past-President, Physicians for Social Responsibility
Jyotsna S. Jagai, MSc, MPH, PhD
Research Assistant Professor
University of Illinois, Chicago

Patricia D. Koman, MPP, PhD
President and Senior Health Scientist
Green Barn Research Associates

Ted Schettler MD, MPH
Science Director
Science and Environmental Health Network

Patrice Sutton, MPH
Research Scientist, Program on Reproductive Health and the Environment
Department of Obstetrics, Gynecology and Reproductive Sciences
University of California, San Francisco