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. Lautenberg 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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[1] US EPA (2019) EPA - PV29 Inhalation Risk Characterization Summary June 6, 2019. Available: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0052

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

[3] UCSF PRHE, et al. (2019) Comments from Academics, Scientists and Clinicians on the Draft Risk Evaluation for C. I. Pigment Violet 29. Available: https://prhe.ucsf.edu/sites/g/files/tkssra341/f/wysiwyg/2019%2001%2014_PV%2029%20Risk%20Eval_UCSF%20PRHE_comments_EPA.pdf

[4] UCSF PRHE, et al. (2019) Comments from Academics, Scientists and Clinicians on Materials Supporting the Colour Index (C. I.) Pigment Violet 29 Risk Evaluation. Available: https://prhe.ucsf.edu/sites/g/files/tkssra341/f/wysiwyg/2019%2005%2017_PV%2029%20Systematic%20Review_UCSF%20PRHE_Comments%20and%20Appendices_EPA.pdf

[5] US EPA (2019) EPA - PV29 Inhalation Risk Characterization Summary June 6, 2019. Available: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0052

[6] US EPA (2018) Draft Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone)

> "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." [7]

EPA's new inhalation analyses rely on numerous assumptions that do not have any supporting empirical data, including that Pigment Violet 29 is: [8]

- 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. [9]

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."[10]

ECHA's findings also counter EPAs claim regarding the insolubility of Pigment Violet 29, calling the solubility "questionable." [11] 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.[12,13,14]

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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[7] US EPA (2019) Draft Risk Evaluation for C.I. Pigment Violet 29 (PV29, CASRN 81-33-4) SACC Peer Review Presentation. pg. 41

[8] US EPA (2019) EPA - PV29 Inhalation Risk Characterization Summary June 6, 2019. Available: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0052

[9] European Chemicals Agency (2019). Justification Document for the Selection of a CoRAP Substance Group Name: Diisoquinoline tetrones Available: https://echa.europa.eu/documents/10162/387374b8-62fa-c857-e60f-65e1cd9fd821

[10] Id. Page 13.

[11] Id. Page 13.

[12] European Chemicals Agency (2019). Community rolling action plan (CoRAP) update covering the years 2019, 2020 and 2021. Page 32. Available: https://echa.europa.eu/documents/10162/13628/corap_update_2019-2021_en.pdf/12451cec-ce6e-d156-5fef-7d09cb77b324

[13] WHO International Agency for Research on Cancer (2010). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Vol 92: Some Non-Heterocyclic Polycyclic Aromatic Hydrocarbons and Some Related Exposures. Available: https://monographs.iarc.fr/wp-content/uploads/2018/06/mono92.pdf

[14] ATSDR 2008. Polycyclic Aromatic Hydrocarbons (PAHs): What Health Effects Are Associated With PAH Exposure? https://www.atsdr.cdc.gov/csem/csem.asp?csem=13&po=11

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,

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