



July 10, 2019

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: Draft: OPPT Updated Risk Characterization for Occupational Inhalation of PV29 Based on Updated Approach (Docket No. EPA-HQ-OPPT-2018-0604)

Dear Administrator Wheeler:

On behalf of the American Public Health Association, a diverse community of public health professionals that champions the health of all people and communities, I appreciate the opportunity to comment on the U.S. Environmental Protection Agency's Draft: OPPT Updated Risk Characterization for Occupational Inhalation of PV29 Based on Updated Approach (Updated Risk Characterization). APHA previously commented on the agency's Draft Risk Evaluation for C. I. Pigment Violet 29 (Draft Risk Evaluation). These comments were prepared in collaboration with the association's Environment Section. Unfortunately, many of the shortcomings of the Draft Risk Evaluation also afflict the Updated Risk Characterization. We continue to respectfully urge EPA to ensure adequate protections for public health by reconsidering its approach to risk evaluation for PV29 and, in particular, to use its statutory authority to acquire additional information.

1. EPA lacks the toxicity and exposure data needed to determine that PV29 does not present an unreasonable risk of injury to health.

A foundational flaw in both the Draft Risk Evaluation and the Updated Risk Characterization is the nearly complete lack of data on PV29 toxicity and exposure. As noted in our comments on the Draft Risk Evaluation, a risk evaluation "depends on estimates of toxicity and exposure and the data used to derive them."¹ Yet EPA lacks data to support either estimate. The agency therefore cannot conclude that PV29 does not present an unreasonable risk of injury to health.

In the Updated Risk Characterization, EPA derived a no-effect concentration for PV29 by extrapolating from a no-effect concentration for barium sulfate, which in turn was extrapolated from a no-effect concentration for titanium dioxide.² EPA did not utilize any data on the inhalation toxicity of PV29 *per se*. The only studies of the inhalation toxicity of PV29 in the agency's possession were

¹ Please see APHA's comments on the Draft Risk Evaluation at 1-2. The comments are available at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0010>.

² Updated Risk Characterization at 2. C. L. Tran *et al.*, Investigation and Prediction of Pulmonary Responses to Dust: Part II, in *Investigations into the Pulmonary Effects of Low Toxicity Dusts: Parts I and II* 105 (1999).

rated “unacceptable” for use in risk assessment by the agency itself.³ EPA also continues to lack reliable measurements of PV29 concentrations in workplace air, which are needed to estimate occupational inhalation of the chemical.⁴

The lack of data did not stop EPA from asserting in the Updated Risk Characterization that PV29 “is a relatively large (MMD=46.9 μm), poorly respirable, poorly absorbed particle, which is not metabolized and not inherently toxic, and exhibits a low solubility.”⁵ EPA has provided little to no support for these claims. Notably, while EPA states that PV29 particles are “relatively large” and “poorly respirable,” its estimate of particle size distribution is based on a manufacturer study that examined bulk material and not the subset of particles in the bulk material that become aerosolized or otherwise airborne in the workplace (and thus potentially inhalable by workers).⁶ While EPA states that PV29 is “not inherently toxic,” as noted above, there are just two studies of PV29’s inhalation toxicity and the agency considers both unacceptable.

2. EPA relies on model inputs that are unsupported by data and likely fail to account for potentially exposed or susceptible subpopulations.

The inputs used to calculate the margin of exposure in the Updated Risk Characterization rely on unfounded assumptions. EPA assumes that just 1.13% of particles inhaled are deposited in the alveoli based on results obtained from the multiple-path particle dosimetry model.⁷ This model depends on the particle size distribution, but as noted above, EPA lacks data on the size distribution of PV29 particles in workplace aerosols. The agency needs to obtain an appropriate particle size distribution and update its analysis of alveolar deposition. The Updated Risk Characterization also assumes that workers will work (and therefore could inhale PV29) for eight hours per day,⁸ while the earlier Draft Risk Evaluation assumes that workers will work for 12 hours per day based on information obtained from a PV29 manufacturer.⁹ EPA has not explained why it reduced the assumed shift length from 12 to eight hours per day, even though a PV29 manufacturer indicated that a typical shift length is 12 hours.

The Toxic Substances Control Act requires EPA to determine whether a chemical presents an unreasonable risk to potentially exposed or susceptible subpopulations, but the agency did not consider any subpopulations in the Updated Risk Characterization. In particular, the agency did not consider workers with respiratory disorders or workers who are pregnant. The proportion of PV29 particles deposited in the alveoli may increase in workers with asthma or chronic obstructive pulmonary disease.¹⁰ The Centers for Disease Control and Prevention estimate that 7.9% and 6.4% of

³ EPA, C.I. Pigment Violet 29 (81-33-4) Systematic Review: Supplemental File for TSCA Risk Evaluation: Data Evaluation Scoring Sheets: Updated Document 22, 25 (2019), available at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0040>.

⁴ EPA uses the OSHA permissible exposure limit for “particulates not otherwise regulated (PNOR)” as the PV29 concentration. Updated Risk Characterization at 1. EPA previously based the PV29 concentration on an unsubstantiated claim by a manufacturer of PV29. Draft Risk Evaluation at 22.

⁵ Updated Risk Characterization at 2.

⁶ Updated Risk Characterization at 1. The study is summarized in BASF, Final Report: Physico-Chemical Properties of “Paliogen Violet 5011” Study No. 11L00105 (confidential), available at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0036>.

⁷ Updated Risk Characterization at 3.

⁸ Updated Risk Characterization at 2-3.

⁹ Draft Risk Evaluation at 22.

¹⁰ Kristin K. Isaacs *et al.*, Chapter VIII: Modeling Deposition of Inhaled Particles 35-36, available at https://cfpub.epa.gov/si/si_public_file_download.cfm?download_id=507922&Lab=NERL.

the U.S. population has asthma¹¹ and COPD,¹² respectively. It therefore is likely that some workers who do or could manufacture or handle PV29 have one or both conditions. Furthermore, inhalation rate increases by approximately 40% in pregnant women,¹³ but EPA utilized a single inhalation rate for all workers (1.25 m³/hour)¹⁴ and failed to consider the known increase expected in pregnant women. EPA must consider risks to potentially exposed or susceptible subpopulations, as required by the statute.

3. EPA failed to apply additional uncertainty factors to account for inadequate data.

EPA lacks sufficient data to conclude that PV29 does not present an unreasonable risk of injury to health. As our comments on the Draft Risk Evaluation urged, EPA “should exercise its authority under TSCA to require the submission of additional studies before it finalizes the risk evaluation.”¹⁵ When the agency lacks necessary data, it should apply appropriate uncertainty factors as described in our earlier comments.¹⁶

Unfortunately, EPA not only did not apply the necessary additional uncertainty factors in the Updated Risk Characterization; it reduced the total uncertainty factor from 100 to 30.¹⁷ The only justification provided for this change is a sentence fragment in a footnote, so the basis for this reduction is unclear. It appears that the agency believes that it has accounted for inter-species differences in the toxicokinetics of PV29. However, it does not appear that EPA has even considered differences between rats (the species in which a no-effect concentration for titanium dioxide, and ultimately PV29, was derived) and humans with respect to particle clearance. As particle clearance may be significantly slower in humans than in rats,¹⁸ EPA must continue to apply an uncertainty factor to account for inter-species differences in toxicokinetics.

EPA cannot support a determination that PV29 does not present an unreasonable risk of injury to health based on the data utilized in the Draft Risk Evaluation and the Updated Risk Characterization. We respectfully urge the agency to acquire the toxicity and exposure data it needs to conduct a proper risk evaluation and safeguard public health.

Sincerely,



Georges C. Benjamin, MD
Executive Director

¹¹ CDC, Most Recent National Asthma Data, https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm.

¹² CDC, Basics About COPD, <https://www.cdc.gov/copd/basics-about.html>.

¹³ Patricia D. Koman *et al.*, Examining Joint Effects of Air Pollution Exposure and Social Determinants of Health in Defining “At-Risk” Populations Under the Clean Air Act: Susceptibility of Pregnant Women to Hypertensive Disorders of Pregnancy, 10 *World Medical and Health Policy* 7, 14 (2008) (citing Matthew J. Hegewald and Robert O. Crapo, Respiratory Physiology in Pregnancy, 32 *Clinics in Chest Medicine* 1, 5 (2011)).

¹⁴ Updated Risk Characterization at 3.

¹⁵ Please see APHA’s comments on the Draft Risk Evaluation at 5.

¹⁶ *Id.* at 4-5.

¹⁷ Updated Risk Characterization at 3.

¹⁸ Gunter Oberdorster, Lung Particle Overload: Implications for Occupational Exposures to Particles, 21 *Regulatory Toxicology and Pharmacology* 123, 125 (1994).