

April 19, 2019

Alexandra Dunn
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC 20460

Re: Continued Withholding of Pigment Violet 29 Health and Safety Studies (EPA-HQ-OPPT-2018-0604)

Dear Assistant Administrator Dunn:

As you know, our organizations have been concerned by EPA's failure to disclose the 24 studies on which the Agency relied in its draft risk evaluation for Pigment Violet 29 (PV29) under the Toxic Substances Control Act (TSCA). In a December 6, 2018 letter from some of our organizations to Principal Deputy Assistant Administrator Beck, we emphasized that section 14(b)(2) of TSCA requires all "health and safety studies" informing the PV29 risk evaluation to be made available to the public. That letter also stressed the importance of timely access to the PV29 studies so that our organizations could review and comment meaningfully on the Agency's proposed determination that PV29 does not present an unreasonable risk of injury to health or the environment.

On March 22, EPA announced a partial release of the 24 studies. Based on this release, your April 17 blog stressed that EPA is "committed to being transparent about chemical information as we work to develop risk evaluations under TSCA" and that you strongly believe that "we must provide for the fullest possible public participation in all of our decision making."

Our review of the studies posted on EPA's website and to the PV29 docket has revealed that EPA has fallen far short of the transparency to which you committed. In particular, the Agency has withheld all but about 100 pages of the 430-page report for the BASF reproductive/developmental toxicity screening study on PV29.¹ The redacted portions of the report include the detailed animal-by-animal observations of reproductive performance and the results of pathology examinations. These data are essential to independently evaluating the study findings regarding the effects of PV29 exposure on the test animals. Importantly, this screening study plays a central role in the draft risk evaluation: its results form the basis for the Margin of Exposure (MOE) analysis that purports to show that PV29 is without harmful effects to workers, a finding that EPA then uses to determine the absence of risk to other exposed subpopulations.

In addition, 10 of the studies (# 1,2, 5-10, 12 and 13) are summarized in a single 10-page report prepared by BASF that lacks adequate supporting data.² The first page of and EPA's own filename

¹ This study is #17 in the EPA table listing the 24 studies. https://www.epa.gov/sites/production/files/2019-03/documents/memo_transmitting_studies_for_pv29_and_attachment_a.pdf. The redacted version of the study can be found at https://www.epa.gov/sites/production/files/2019-03/documents/study_17_repro-dev_toxicity_non-confidential.pdf.

² https://www.epa.gov/sites/production/files/2019-03/documents/study_s_1_2_5-10_12_13_toxicological_investigation_summaries_non-confidential.pdf.

assigned to this document use the word “summary” and “summaries,” respectively, to describe its contents. These 10 summaries are even shorter than the robust summaries of these studies cited by EPA in its draft risk evaluation, and clearly do not constitute the “full study reports” that EPA claimed it possessed and had reviewed. This set of facts suggests either that EPA does not have the full study reports and is relying on these summaries prepared by the data owner in its risk evaluation, or that EPA does have the full study reports and is still not making them publicly available. Neither scenario is acceptable.

Your April 17 blog also announces that EPA is reopening the PV29 comment period for 30 days “in light of the new and updated information we’ve recently released.” However, without the data tables from the reproductive/developmental toxicity screening study and any full study reports from the 10 summarized studies, it remains impossible to evaluate whether these studies’ reported findings accurately reflect their results. Thus, the public will be unable to comment fully on whether the studies support EPA’s claim that PV29 does not pose unreasonable risk, including a developmental or reproductive risk.³ Nor is it currently possible to provide informed feedback to the Scientific Advisory Committee on Chemicals (SACC) when it considers these studies during its peer review of the PV29 risk evaluation.

EPA’s withholding of critical health and safety data from public review is not only inconsistent with the very purpose of a public comment period, but also directly contrary to TSCA. EPA claims that the redacted data constitutes “confidential” information that was voluntarily provided to EPA by a foreign chemical manufacturer. However, TSCA section 14(b)(2)(A) expressly prohibits EPA from withholding “health and safety studies submitted under this Act” as confidential, affirming the public’s right to know the health and safety effects of the chemicals that it is exposed to. Here, EPA requested the PV29 studies for the express purpose of conducting its risk evaluation under TSCA, the studies were shared with EPA with the explicit understanding that they would be used to carry out the Agency’s TSCA responsibilities, and EPA relies on the studies throughout its draft risk evaluation. Accordingly, they are, under any definition of the term, “health and safety studies submitted under” TSCA. As House Energy and Commerce Committee Chair Frank Pallone and Subcommittee Chair Paul Tonko emphasized in their [March 21 letter to EPA Administrator Wheeler](#), to create an exemption from disclosure for such information despite the clear language of the statute is “to skirt the balanced system of CBI protection established by the Lautenberg Act” and “to mask health and safety information used under TSCA.”

TSCA section 14(b)(2)(B) independently requires the disclosure of “any information reported to, or otherwise obtained by, the Administrator from a health and safety study” on a chemical offered for distribution in commerce. EPA does not, and cannot, deny that the data withheld from the PV29 studies constitutes information obtained by EPA from a health and safety study of a commercially-available chemical.

The Agency’s approach to the PV29 studies has troubling implications for the transparency of future TSCA risk evaluations. Many chemicals that are and will be candidates for risk evaluations under TSCA have been the subject of health and safety studies conducted by foreign chemical manufacturers. If EPA

³ We are still evaluating the redactions in the other studies but these too may impede meaningful public comment the risk evaluation.

could rely on those studies in its risk evaluations without disclosing them for public review, or release only such data from these studies as industry approves, then public participation in chemical safety decisions under TSCA would be held hostage to the willingness of chemical manufacturers to share their data with the public. That plainly is not what Congress intended when it enacted section 14(b)(2), and it would deny the public a meaningful opportunity to comment on key EPA scientific findings that rely on industry-supplied data. The credibility of future EPA priority listings and risk evaluations will be seriously impaired if they are based on scientific studies that, in whole or in part, are withheld from the public.

Industry has warned that it will not provide EPA with health and safety studies conducted outside the US on chemicals subject to future risk evaluations if EPA does not commit to shielding such studies from public review.⁴ This threat cannot justify compromising the transparency that Congress required under TSCA section 14(b). If industry chooses not to share test data relevant to TSCA risk evaluations, EPA has ample authority to require US manufacturers and importers to develop and submit such information under section 4(a)(2), which authorizes EPA to issue test orders or rules “necessary . . . to perform a risk evaluation” or for “prioritizing a chemical substance.” Studies conducted pursuant to EPA’s use of these authorities would need to be disclosed to the public under the plain language of section 14(b)(2).

In sum, we urge you to reconsider EPA’s continued unlawful withholding of health and safety data on PV29 despite the plain language of section 14(b)(2). Such withholding will compromise the transparency that is vital to the credibility of EPA’s risk evaluations for this substance and others that will be assessed under TSCA in the future.

Please contact Robert Sussman, counsel for Safer Chemicals Healthy Families, with any questions at bobsussman1@comcast.net.

Respectfully submitted,

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⁴ BASF Colors & Effects Switzerland AG, Letter to Scott Sherlock, EPA, regarding FOIA Request No. EPA-HO-2019-001853, February 5, 2019.

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