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Concerns About EPA Not Using Its Authority Under TSCA While Conducting a Draft Evaluation for PV29

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On March 22, 2019, EPA **announced** the release of the **24 studies** used by EPA to develop the draft risk evaluation for Pigment Violet 29 (PV29) and reopened the comment period**.** EPN has the following concerns:

1) The lack of transparency in this risk evaluation will create a precedent of making "no unreasonable risk" determinations based on proprietary information.
2) The most critical study in this evaluation was heavily redacted, which removes the ability to do an independent analysis.
3) A potentially useful and important study was not included in the draft risk evaluation, with no explanation.

As background, on November 15, 2018, EPA's Office of Pollution Prevention and Toxics (OPPT) **issued** a draft risk evaluation of PV29 for public review and **comment.** It was the first in the series of the initial 10 existing chemicals to have a draft risk evaluation released by the current administration under the new priority-setting/evaluation system described in the 2016 updated Toxic Substances Control Act (TSCA). Unlike the other nine on the list, PV29 is a substance for which the extant database is constituted solely of toxicity, physical/chemical characteristics, and environmental fate studies declared by its manufacturer (BASF) to be Confidential Business Information (CBI), making them unavailable for EPA's draft risk evaluation. EPN members, along with many others, submitted **comments** on the TSCA risk evaluation of PV29, highlighting the improper use of TSCA CBI discretion, which led the agency to release the aforementioned 24 studies.

Setting an Unwanted Precedent: TSCA gives EPA the authority to require testing that will not be held as CBI before a determination of "no unreasonable risk" is made. EPA is not using that authority in this case, and presumably won't do so in future cases. EPN urges the agency to use its authority and not make a determination based on proprietary information, which could endanger public health and the environment. In the case of PV29, making these data fully available may or may not change EPA's determination, but for other chemicals in the pipeline, relying heavily on confidential data might make a significant difference. EPN urges the agency to use its authority and not make a determination based on proprietary information.

Critical Study Was Heavily Redacted: EPA released documentation on the studies in March 2019, with some redactions. In one case (Study #17, the rat reproduction/developmental screening study), the raw data for each individual animal, which form the basis of the summaries, is blacked out, so one cannot conduct an independent analysis of the data. In addition, no justification was provided for redacting the individual animal data.

Potentially Useful Study Was Not Included: Without explanation, EPA did not include a review of, or reference to, a 90-day repeated dose dietary study in rats.