

SUMMARY

EPN's Third Set of Comments Objecting to EPA'S Draft Risk Evaluation of Pigment Violet 29 under the Toxic Substance Control Act

July 10, 2019

On July 10, 2019, EPN submitted its [comments](#) on EPA's April 2019 supplemental file for the risk evaluation of Pigment Violet 29 (PV29) under the Toxic Substances Control Act (TSCA). PV29 is primarily used as a colorant in inks, paints, coatings and plastic. This is the third set of comments EPN has submitted objecting to the process followed and basis on which EPA conducted the risk evaluation of PV29 - the first evaluation of a chemical since TSCA was reformed in 2016. EPN once again urges EPA not to make a determination on PV29, or any chemical, based on proprietary information -- a precedent-setting decision that could endanger public health and the environment.

Today's EPN comments respond to a June 2019 EPA [memorandum](#) announcing the opening of public comments on its PV29 inhalation risk characterization summary and updated "charge" questions for a then upcoming meeting of the Science Advisory Committee on Chemicals. This set of EPN comments emphasize issues with:

- **The TSCA systematic review process used.** The current systematic review process has never been externally peer-reviewed. EPN recommends that EPA stop using the TSCA systematic review process until it has been formally peer reviewed and revised to follow accepted scientific principles.
- **The adequacy of the PV29 database and the missing uncertainty factor.** The approach to determine hazardous levels of exposure was computed with four uncertainty factors, missing a crucial fifth to account for database deficiencies.,
- **The testing necessary under TSCA for information to be sufficient.** EPA relied on inadequate data to reach the conclusion that PV29 does not present an unreasonable risk to health or the environment. EPA should not be deterred from using its authority to require testing by rule, order or consent agreement when data are needed to conduct a risk evaluation or even to establish the priority of a chemical for risk evaluation.

The risk evaluation of PV29 is critical because it will be seen as precedent setting. EPA needs to establish criteria to determine the minimum data set necessary to make a risk determination. Without such criteria, it will appear to be an arbitrary judgment call on each chemical.

As background, the draft "TSCA Risk Evaluation for Colour Index (C. I.) Pigment Violet 29 (PV29)" was originally [published](#) in the *Federal Register* in November 2018. Initially, EPA refused to make the underlying health and safety studies for PV29 public, and only provided copies of and links to brief summaries that were prepared by companies that make PV29. EPA claimed the studies had to be withheld because they were protected as confidential business information under TSCA. In January 2019 EPN issued its [first set of comments](#) on the risk evaluation, focusing on the use of a flawed process, the issue of insufficient information, and overlooked paths of exposure. EPN members also highlighted the improper use of confidential business information under TSCA.

Thanks to EPN's comments and those of others, in March 2019, EPA released [24 studies](#) used by EPA to develop the draft risk evaluation for PV29 and reopened the comment period. EPN analyzed the studies used in the evaluation and others not used. EPN's [comments](#) on the 24 studies noted the continued lack of transparency, the exclusion of an important study, and the heavy redaction of the most critical study.