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SUMMARY

EPN's Comments on EPA'S Revised Draft Risk Evaluation of Pigment Violet 29 under the Toxic Substance Control Act

December 19, 2020

On December 19, 2020, EPN submitted comments on EPA's revised risk evaluation of Pigment Violet 29 (PV29), conducted under the Toxic Substances Control Act (TSCA). PV29 is primarily used as a colorant in inks, paints, coatings, and plastic. EPN previously submitted three sets of comments 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 vigorously objects to several aspects of this review process, which was originally slated for a 30-day comment period, since extended 20 days until December 19, 2020. First, the concurrent peer review should occur after the public comment period so that peer reviewers are able to take into consideration public comments. Also, the draft revised risk evaluation is essentially a brand new document, now including new key sections that were not addressed substantively in the original draft. This document should be sent back to the full Science Advisory Committee on Chemicals for peer review, and several experts on inhalation toxicology, which is the most critically required expertise for this risk evaluation, should be added to the peer reviewers.

In addition, EPN comments emphasize issues with the following:

Overall Comments:

- EPA did not require health effects studies for PV29, which were previously recommended by EPN and other commenters.
- EPN is concerned that the updated EPA evaluation still significantly underestimates PV29's risks to workers.
- EPA lacks a basis on which to determine that PV29 is without health effects other than lung toxicity following inhalation, and must require testing to make informed judgments on this issue.

The Charge Questions:

- It is not possible to answer the question of EPA's initial conclusion of "no unreasonable risk" for PV29 in the absence of additional, relevant toxicity testing.
- The data EPA uses for inhalation exposure estimates have substantial limitations, leading to a number of uncertainties. They are not adequate for use in any credible exposure assessment and should be replaced with new data.
- EPN believes EPA should require a subchronic (90-day) inhalation study in rodent(s) along with appropriate shorter term *in vivo* and/or *in vitro* studies designed to characterize the mode of action of the lung effects and examine the potential for carcinogenicity in PV29.

Additional Comments:

- **Human Health Risk Characterization:**
  - **Margin of Exposure:** Among other deficiencies, EPN once again pointed out that there is a missing uncertainty factor (UF), which accounts for data deficiencies. This omission runs counter to agency guidance, and in this case, the database for PV29 is so lacking that this UF should be set as its maximum default of 10X.
  - **Risk Estimation:** EPA underestimates the risk to workers by assuming they will use personal protective equipment (PPE), such as respirators, during all of their work throughout their careers, even when such equipment is not required, provided or used. EPN believes EPA should not consider the use of PPE in making unreasonable risk determinations for workers and occupational non-users.

Background

TSCA was passed in 1976 to keep dangerous chemicals off the market and protect people from exposure to existing chemicals. It was amended and strengthened in 2016, requiring EPA to set priorities for which chemicals to assess, evaluate their risks and impose restrictions to protect people's health and the environment.