
# Draft Risk Evaluation for Pigment Violet 29

## December 12, 2018

KELLER AND HECKMAN LLP
SERVING BUSINESS THROUGH LAW AND SCIENCE®


# Please Don't Forget to Dial-In:

## Conferencing Number: (800) 768-2983

## Access Code: 434 4318

**(View the slides via webinar, and hear the sound via phone)**

KELLER AND HECKMAN LLP

SERVING BUSINESS THROUGH LAW AND SCIENCE®

# Herbert Estreicher, J.D., Ph.D.

Herbert Estreicher, J.D., Ph.D. has a broad practice in international environmental regulatory law. He has an interdisciplinary approach combining law and science. He represents leading manufacturers of chemicals, pesticides, insect repellents, food additives, and consumer products before Federal and State regulatory agencies. He helps clients secure and maintain chemical approvals and pesticide registrations in the U.S., Canada, Europe, and Korea, advises clients on TSCA Reform, the CEPA challenge program, Korea REACH, and provides advice on European chemical directives and initiatives, such as the EU Biocidal Products Regulation, and the EU REACH regulation.

**estreicher@khlaw.com • 202.434.4334**

# John B. Gustafson

John Gustafson practices in the environmental, workplace safety and health, and litigation groups at Keller and Heckman. Specifically, John addresses issues that arise under FIFRA, TSCA, the OSH Act, California Proposition 65, and in standards development organization and labor and employment contexts.

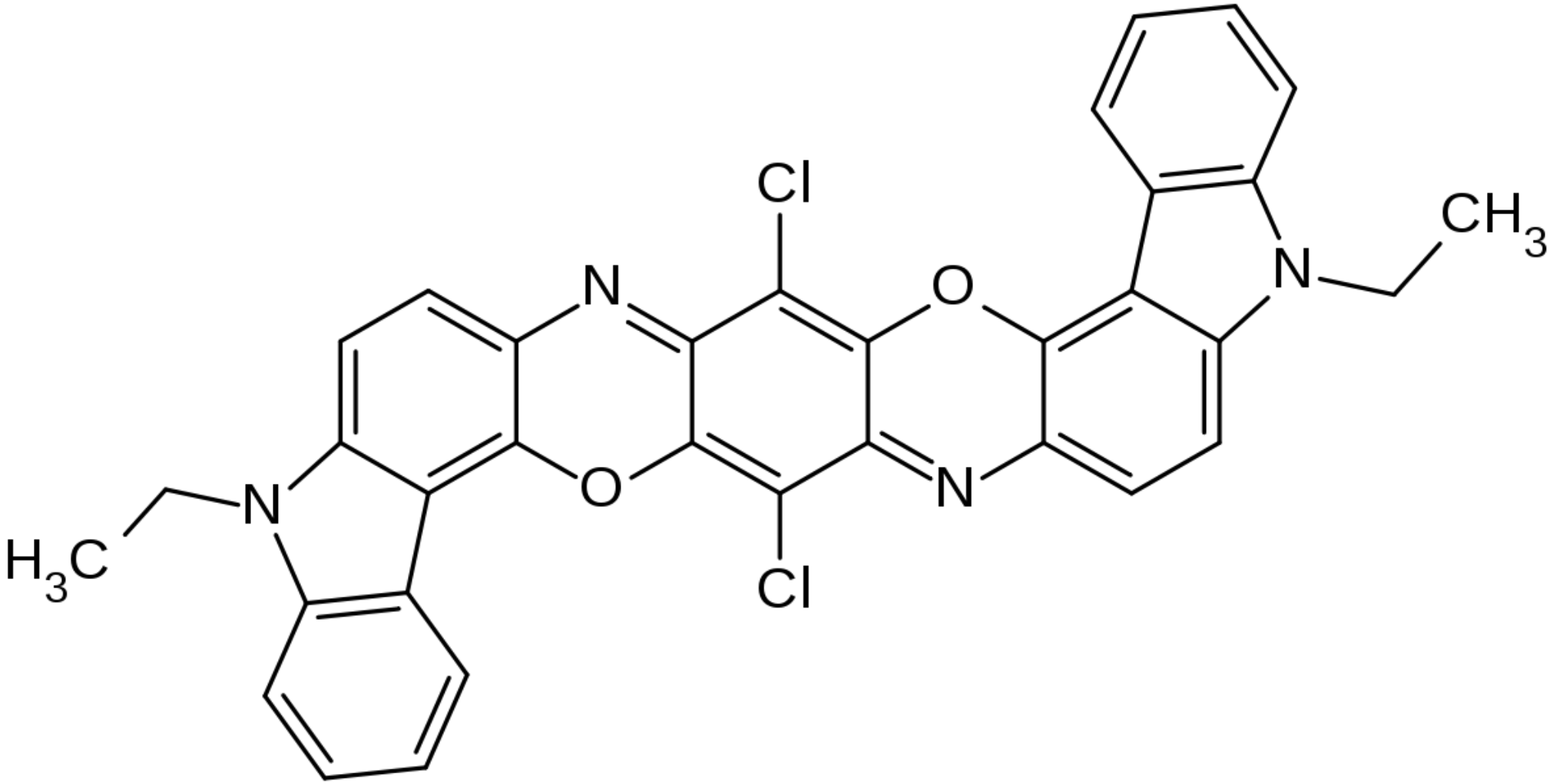
John also assists clients on litigation matters and has experience in both trial and appellate settings.

**gustafson@khlaw.com • 202.434.4204**

# Today's Topics

- EPA's First TSCA Draft Risk Evaluation – Pigment Violet 29
- Systematic Review
- NGO Reaction
- The Risk Evaluation Peer Review Process
- Final Thoughts

# CI Pigment Violet 29, CAS No. 81-33-4



- Docket: EPA-HQ-OPPT-2018-060.
- Public comment for 60 days until January 14, 2019.

# Uses

- Pigment Violet 29 is used to color materials **and as an intermediate** for other pigments.
- About 90% of the volume is as a site-limited intermediate.
- The remaining 10% is used in commercial paints or coatings or commercial plastic and rubber products.
- An unknown volume of C.I. Pigment Violet 29 is used in **consumer watercolor and acrylic paints.** This use of C.I. Pigment Violet 29 in artistic paint products is reported to comprise less than 1 percent of total sales.

# Hazard Assessment

- **Reasonably available data** indicates **no aquatic toxicity** up to the limit of solubility of the chemical.
- **No adverse effects for human health for all routes of exposure** (oral, dermal, inhalation).
- C.I. Pigment Violet 29 is **negative for genotoxicity**.
- Structural activity relationships (SAR) considerations support conclusion that C.I. Pigment Violet 29 is **unlikely to be a carcinogen**.
- Based on the human health and environmental toxicity testing, the EPA concludes that C.I. Pigment Violet 29 presents a **low hazard to human health and the environment.**

# Exposure Assessment

- EPA conducted a **qualitative assessment** of potential environmental, consumer and general population exposures.
- **Assessment based on physical-chemical properties**, which includes low solubility, low vapor pressure, low bioaccumulation potential, and poor absorption across all routes of exposure; as well as manufacturing information, which indicates that environmental releases from the conditions of use are limited.
- The EPA also conducted a **quantitative screening-level assessment** of **occupational exposure** using a high-end estimate of inhalation and dermal exposure.
- **Qualitative and quantitative considerations** of physical chemical data, environmental fate data, manufacturing, and use information indicates that **exposures are expected to be limited for the conditions of use** of C.I. Pigment Violet 29.

# Occupational Exposure

- **INHALATION EXPOSURE**
- High-end exposure analysis was performed to represent a theoretical high-end exposure of C.I. Pigment Violet 29 at a manufacturing site.
- Using the air monitoring data from the one manufacturing site (0.5 mg/m3 over 12 hours/day) and converting to an inhalation Potential Dose Rate (PDR) for workers is 7.5mg/day using the following equation:

***(0.5 mg/m3 x 1.25 m3/hour x 12 hours/day) = 7.5mg/day***

Where:

0.5 mg/m3= **Manufacturer-provided workplace air monitoring results for total workplace dust** (this conservatively assumes that 100 percent of the total dust is C.I. Pigment Violet 29)

1.25 m3/hour= **EPA default assumption of respiration rate**

12 hours/day= **Assumed maximum shift length**

- **DERMAL EXPOSURE**
  - screening-level assessment
  - the dermal potential dose rate for workers is assumed to be the theoretical maximum exposure of 3100 mg/day, which is the worst-case assumption used by the EPA for dermal exposure based on 2-hand dermal contact with solids without gloves.

# Heavy Use of EU REACH Data

- EPA obtained 24 **full study reports** associated with the European Chemicals Agency (ECHA) robust summaries and used them to make a preliminary determination of hazard during problem formulation.
- EPA reviewed these **full study reports** and assessed the quality of the methods and reporting of results of the individual studies using the evaluation strategies described in **Application of Systematic Review in TSCA Risk Evaluations** and concluded that they are of high or medium quality.
- Of note the Registration Dossier is now undergoing a “comprehensive” compliance check by ECHA: https://www.echa.europa.eu/web/guest/information-on-chemicals/dossier-evaluation-status/-/dislist/details/0b0236e182994514

# International Laws and Regulations

- Heavy emphasis on Environment Canada review
- Canadian Ecological Risk Classification for C.I. Pigment Violet 29 determined that C.I. Pigment Violet 29 did not meet the criteria for categorization as a prioritized substance for further evaluation and the potential hazard is low (Environment Canada, 2006).
- The conclusion of Canada's screening indicated that because of low toxicity and low solubility C.I. Pigment Violet 29's hazard potential is low (Environment Canada, 2006).
- EPA also looked at status in other countries including Australia, China, EU, Korea, Taiwan and the Philippines.

# Systematic Review

- Structured process of identifying, evaluating and integrating evidence for both the hazard and exposure assessments developed during the TSCA risk evaluation process.

  https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf

# Example of Systematic Review

| Domain | Metric | Qualitative Determination [i.e., High, Medium, Low, Unacceptable, or Not rated] | Metric Score | Metric Weighting Factor | Weighted Score (Metric Score x Metric Wt. Factor)1 |
|---|---|---|---|---|---|
| **Test Substance** | 1. Test Substance Identity | High | 1 | 2 | 2 |
| | 2. Test Substance Purity | High | 1 | 1 | 1 |
| **Test Design** | 3. Study Controls | High | 1 | 2 | 2 |
| | 4. Test Substance Stability | High | 1 | 1 | 1 |
| **Test Conditions** | 5. Test Method Suitability | High | 1 | 1 | 1 |
| | 6. Testing Conditions | High | 1 | 2 | 2 |
| | 7. Testing Consistency | High | 1 | 1 | 1 |
| | 8. System Type and Design | N/A | N/A | N/A | N/A |
| **Test Organisms** | 9. Test Organism - Degradation | High | 1 | 2 | 2 |
| | 10. Test Organism - Partitioning | N/A | N/A | N/A | N/A |
| **Outcome Assessment** | 11. Outcome Assessment Methodology | High | 1 | 1 | 1 |
| | 12. Sampling Methods | High | 1 | 1 | 1 |
| **Confounding/ Variable Control** | 13. Confounding Variables | Medium | 2 | 1 | 2 |
| | 14. Outcomes Unrelated to Exposure | Medium | 2 | 1 | 2 |
| **Data Presentation and Analysis** | 15. Data Reporting | High | 1 | 2 | 2 |
| | 16. Statistical Methods & Kinetic Calculations | Medium | 2 | 1 | 2 |
| **Other** | 17. Verification or Plausibility of Results | High | 1 | 1 | 1 |
| | 18. Other | High | 1 | 1 | 1 |
| | 18. QSAR Models | N/A | N/A | N/A | N/A |
| | | **Sum of scores:** | 19 | 21 | 24 |
| | | **Overall Score = Sum of Weighted Scores/Sum of Metric Weighting Factors:** | 1.143 | **Overall Score: (Rounded** | 1.1 |
| | | | **Overall Quality Level:** | | **HIGH** |

# NGO Reaction

- Environmental, academic and public health groups urged EPA in comments on the Problem Formulation Document to **require new toxicity tests** of the chemical.
- They argued that EPA had **insufficient information** to conduct an assessment of **adequate quality** to meet the revised TSCA's standards.
- "EPA **could not reach scientifically defensible conclusions** that [PV29] lacks the potential to cause carcinogenicity, reproductive and developmental toxicity, developmental neurotoxicity, neurotoxicity, repeated dose toxicity or endocrine effects."
- **"EPA does not have empirical data on the carcinogenicity of [PV29], nor on developmental neurotoxicity or endocrine activity, both of which are relevant to teratogenesis, behavioral disorders and birth defects**."
- "[T]he evidence base for [PV29] hazards is **completely inadequate**."

# § 6 Risk Evaluation Peer Review Process

- Draft Risk Evaluation will be peer-reviewed by the Science Advisory Committee on Chemicals (SACC) in public meeting: January 29 – February 1, 2019
- TSCA imposes no specific peer review requirement for existing chemical risk evaluations (§§ 6, 26)
- § 26(h)(5) requires EPA to consider the extent to which information used has been peer-reviewed; distinct from review of evaluation itself

# § 6 Risk Evaluation Rule

- EPA promulgated peer review regulation, 40 C.F.R. § 702.45, in the Risk Evaluation Rule (82 Fed. Reg. 33744, July 20, 2017)
- 702.45: EPA will conduct peer review using The *EPA Peer Review Handbook* and OMB Bulletin as guidance
- Risk Evaluation Rule preamble states that EPA:
  - "May" use SACC
  - Will not seek review on ultimate unreasonable risk determination during peer review

# Science Advisory Committee on Chemicals

- § 26(o) TSCA – requires establishment of SACC within one year of Lautenberg
- SACC Purpose is to provide *independent* advice and expert consultation
- TSCA requires balanced SACC composition – "representatives of such science, government, labor, public health, public interest, animal protection, industry" and experts on exposed subpopulations
- EPA must convene SACC at least once every two years

# Science Advisory Committee on Chemicals (cont.)

- Composition:
  - Academia – 11
  - Industry – 6
  - Government – 5
  - NGO – 3, including Chair of SACC
  - Standard Development Organization – 1
- October 2018 – EPA requested ad hoc participation nominations

# SACC Public Meeting and Charging Questions

- January 29 – February 1, 2019
- Review of risk evaluation *contents,* which EPA will use in its final risk evaluation decision
- Standards of review – consistent with:
  - "Best available science" § 26(h)
  - "Weight of the evidence" § 26(i)
  - *See* Data Evaluation Scoring Sheets

Docket: EPA-HQ-OPPT-2018-0604

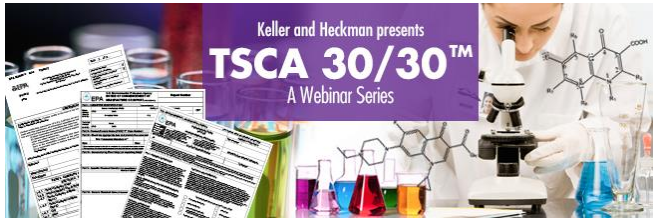
# Public Meeting and Prep Meeting Deadlines

- EPA holding virtual “preparatory” meeting on January 8, 2019
- January 4, 2019, 12 pm – requests to make oral comments in prep meeting due
- January 7, 2019 – written scope/clarity comments for prep meeting due
- January 14, 2019 – requests to make oral comments and substantive comments themselves due for full public meeting
- Meeting details – 83 Fed. Reg. 61629 (November 30, 2018)

# Why Violet Pigment 29?

- The entire risk evaluation, including references and tables, is 43 pages.
- One wonders why this chemical was selected to be among the first 10 evaluated given its low production, exposure and risk profile.
- But the draft provides an example of how the agency will approach these assessments.
- EPA's acting administrator Andrew Wheeler has said that the publication of the first of the 10 draft risk assessments "shows that the agency is delivering on its promise to meet the statutory deadlines and ensure the safety of chemicals currently on the market" under the amended TSCA.
- SACC proceeding will be of interest.


Please join us at 1:00 PM Eastern U.S.
Wednesday, December 19, 2018
www.khlaw.com/OSHA3030




Please join us at 1:00 PM Eastern U.S.
Wednesday, January 9, 2019
www.khlaw.com/TSCA3030


Check our website for updates
or subscribe by emailing
info@khlaw.com


**The Next TSCA 30/30:**
Wednesday, January 9, 2019

For more information on past and future **TSCA 30/30** programs, please visit **www.khlaw.com/tsca3030** and **www.TSCAReformCenter.com** for the most up-to-date TSCA news


# THANK YOU

**Estreicher@khlaw.com**
**202.434.4334**

**Gustafson@khlaw.com**
**202.434.4204**