Published on *The National Law Review* https://natlawreview.com

EPA Completes Final Risk Evaluation for PV29, Finding Unreasonable Risks to Workers and ONUs from Ten Uses

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Government Regulation

The U.S. Environmental Protection Agency (EPA) announced on January 14, 2021, the release of the final risk evaluation for C.I. Pigment Violet 29 (PV29) under the Toxic Substances Control Act (TSCA), meeting a "major chemical safety milestone." In the risk evaluation, EPA reviewed 14 conditions of use for PV29, including as an intermediate for other perylene pigments, as well as a component of paints, coatings, industrial carpeting, and plastic and rubber products used primarily in the automobile industry, in ink used for commercial printing, and in consumer watercolors and artistic paints. EPA determined that there are unreasonable risks to workers and occupational non-users (ONU) from ten out of 14 conditions of use. EPA found no unreasonable risks to the environment, consumers, or the general public. The risk evaluation for PV29 is the final one to be completed (excluding the supplemental risk evaluation that EPA is undertaking for legacy uses of asbestos) for the first ten chemicals under TSCA as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act).

EPA's next step in the process required by TSCA is to develop a plan to reduce or eliminate the unreasonable risks found in the final risk evaluation. EPA states that it "is moving immediately to risk management for this chemical and will work as quickly as possible to propose and finalize actions to protect against the unreasonable risks." The potential actions that EPA could take to address these risks include regulating how PV29 is used or limiting or prohibiting the manufacture, processing, distribution in the marketplace, use, or disposal of PV29, as applicable.

Background

As frequent readers know, TSCA Section 6, as amended by the Lautenberg Act, requires EPA to conduct risk evaluations to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." The statute identifies the minimum components EPA must include in all risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. Each risk evaluation must also: (1) integrate and assess available information on hazards and exposure for the conditions of use of the chemical

substance, including information on specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposure. The risk evaluation must not consider costs or other nonrisk factors. A detailed summary and analysis of the final risk evaluation rule is available in our June 26, 2017, memorandum, "EPA Issues Final TSCA Framework Rules."

Risk Evaluation for PV29

According to the final risk evaluation, PV29 is currently manufactured, processed, distributed, used, and disposed of as part of industrial, commercial, and consumer conditions of use. Leading applications for PV29 include use as an intermediate to create or adjust color of other perylene pigments, incorporation into paints and coatings used primarily in the automobile industry, incorporation into plastic and rubber products used primarily in automobiles and industrial carpeting, use in merchant ink for commercial printing, and use in consumer watercolors and artistic colors. EPA notes that there were no changes to the conditions of use since the revised draft risk evaluation. EPA evaluated the following categories of conditions of use: manufacturing; processing; distribution in commerce; industrial, commercial. and consumer uses; and disposal.

The revised draft risk evaluation included the addition of data from 24 full study reports and associated systematic review that were originally considered as confidential business information (CBI); two sets of particle size distribution data for PV29; two sets of data for breathing zone monitoring of dust in the Sun Chemical Corporation workplace; and solubility testing in water and octanol. EPA received some of the added data used in the revised draft risk evaluation under two TSCA Section 4(a)(2) test orders including solubility testing of PV29 in water and octanol, and dust monitoring study of particulates not otherwise regulated (PNOR) at the Sun Chemical Corporation workplace (the sole U.S. manufacturing site).

EPA made the following risk evaluation findings. EPA stated that in making these unreasonable risk determinations, it considered the hazards and exposure, magnitude of risk, exposed population, severity of the hazard, uncertainties, and other factors.

- **EPA found unreasonable risk to workers and occupational non-users from ten out of 14 conditions of use**. EPA found unreasonable risks to workers and ONUs from seven manufacturing, processing, and disposal uses of PV29. Additionally, EPA found unreasonable risks from three industrial and commercial uses of PV29 to workers and ONUs. This includes an unreasonable risk to workers and ONUs when used in domestic manufacturing or import of PV29; incorporation into formulation, mixture, or reaction products in paints, coatings, plastic, and rubber products; use as an intermediate for other perylene pigments; use in paintings and coatings in the automobile sector and merchant ink for commercial printing; recycling; and disposal. According to EPA, risks to workers and ONUs can come from long-term inhalation exposure;

- **EPA found no unreasonable risk to consumers, bystanders, or the general population**. EPA has determined that there is no unreasonable risk to consumers who use watercolor and acrylic paints containing PV29. Given limited exposure to PV29, EPA has also determined that this chemical does not present an unreasonable risk to the general population from all conditions of use, based on the risk estimates, the exposures, physical-chemical properties,

and consideration of uncertainties; and

- **EPA found no unreasonable risk to the environment for any conditions of use**. EPA has determined that PV29 does not present an unreasonable risk to the environment (aquatic, sediment-dwelling, and terrestrial organisms) from all conditions of use, based on the risk estimates, the environmental effects, the exposures, physical-chemical properties, and consideration of uncertainties.

Commentary

We commend EPA's completion of the TSCA Section 6(b) risk evaluation for PV29. With the completion of this risk evaluation, among the initial ten chemicals selected by EPA for risk evaluation under TSCA as amended by the Lautenberg Act, only Part 2 of the risk evaluation for asbestos, which will cover legacy uses of asbestos, remains to be issued in final.

Risk management efforts will now commence on PV29 covering the conditions of use for which EPA found unreasonable risk. EPA is required to issue a final Section 6(a) regulation within three and one half years of the completion of the risk evaluation, including potentially available extensions. In addition, for the EPA determinations that certain conditions of use do not present an unreasonable risk, these decisions, which EPA issued by order under Section 6(i)(1) of TSCA as part of the risk evaluation, represent final agency actions that are subject to legal challenge.

Notably, in this risk evaluation EPA included exposure to the general population that might otherwise fall under the jurisdiction of other environmental statutes administered by EPA. This is unique among the risk evaluations completed to date; in the other nine risk evaluations, certain exposure pathways were not evaluated because they fall under the jurisdiction of other environmental statutes administered by EPA and are appropriately managed by those statutes. Although EPA does not so state, EPA may have come to this conclusion because PV29 is not identified in its other regulations as a substance that requires restrictions. EPA's primary change in its risk evaluation relate to inhalation of respirable particles. In EPA's draft risk evaluation, EPA found no unreasonable risk under any conditions of use. EPA received updated particle size data from the only manufacturer in the United States that demonstrated that PV29 as manufactured in the United States was below 100 nm. All particle size data prior to that showed PV29 as greater than 40 µm. The smaller particle size led EPA to reconsider its view that PV29 was low hazard for health. With the particles being in the respirable size, EPA reevaluated the hazard of PV29 and evaluated exposures to quantify a Margin of Exposure (MOE). Notably, EPA predicted unreasonable risk for workers and ONUs if those employees do not use respiratory protection with Assigned Protection Factors (APF) of 50 -- a tight-fitting, full-face respirator.

Given that EPA found unreasonable risk for ONUs -- employees that normally do not use respiratory protection because they are not spending extended periods of time being exposed to the substance -- EPA may not be able to protect workers with a requirement to use a respirator with an APF of 50. It is more likely that EPA will set an inhalation exposure limit (presumably as an 8-hour time-weighted average (TWA)), perhaps as low as 0.065 mg/m^3, to ensure that workers without respirators will be protected.

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