

DAVID MICHAELS PhD, MPH
Department of Environmental and Occupational Health
Milken Institute School of Public Health
The George Washington University
950 New Hampshire Ave NW
Washington, DC 20052
dmm@gwu.edu

January 14, 2019

Nancy B. Beck, PhD
Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Re: Draft Toxic Substances Control Act Risk Evaluations: Colour Index Pigment Violet 29
ID: EPA-HQ-OPPT-2018-0604-0001

Dear Dr. Beck:

I am writing to comment on EPA's Draft Risk Evaluation for C.I. Pigment Violet 29.

I am an epidemiologist and Professor of Environmental and Occupational Health at the Milken Institute School of Public Health of George Washington University. The views expressed in these comments are my own and do not represent the views of George Washington University. From 2009 until January 2017, I served as Assistant Secretary of Labor for the Occupational Safety and Health Administration, the longest serving Assistant Secretary in OSHA's history. From 1998 to 2001, I was Assistant Secretary for Environment, Safety and Health in the U.S. Department of Energy, charged with protecting the workers, community residents and environment in and around the nation's nuclear weapons complex.

In this comment, I am specifically addressing the conclusions EPA has reached about worker exposures and the assumptions on which these conclusions are based. It is simply not possible to judge the accuracy of the risk evaluation because the EPA has not provided the 24 key studies used by EPA in the evaluation. This is ironic in that in the EPA's proposed rule "Strengthening Transparency in Regulatory Science" (EPA-HQ-OA-2018-0259), the agency proposes to limit its decision-making to studies whose underlying data and methods are made publicly available, while for this risk evaluation, EPA does not even provide public access to the studies it has used, to say nothing of the underlying data.

Incorrect Assumptions about the Role of SDSs in Worker Protection

On page 10 of the Draft Risk Evaluation, EPA states:

The Safety Data Sheet (SDS) for C.I. Pigment Violet 29 lists recommended engineering controls to minimize workplace exposure to C.I. Pigment Violet 29. Engineering controls

for C.I. Pigment Violet 29, as stated directly in the SDS, include adequate ventilation, processing enclosure, and local exhaust ventilation or other engineering controls. Personal protective equipment (PPE) includes safety glasses with side-shields, dust goggle under certain circumstances, chemical resistant impervious gloves, and particulate respirators if needed (BASF, 2017; CPMA, 2017a; Sun Chemical, 2017).

The EPA has not provided the actual SDSs referenced, but I was able to locate a “Product Safety Datasheet” applicable to a group of chemicals including C.I. Pigment Violet 29.¹ It notes that in Germany, this chemical is covered by the MAK (Germany’s Occupational Exposure Limit) for “alveolar passing dust fraction.”

The most effective way to control dust in the workplace environment is through engineering controls. The “hierarchy of controls” is a widely-recognized and long-standing industrial hygiene principle, applied in all of OSHA’s comprehensive workplace chemical exposure standards. The basic approach can be summarized as: “fix the workplace, not the worker.”

In 2016, OSHA communicated this to EPA in its comments on EPA’s Proposed Rule: “Significant New Uses of Chemical Substances: Updates to the Hazard Communication Program and Regulatory Framework.” The letter, which I signed as Assistant Secretary of Labor for OSHA, supports the requirement that the hierarchy of controls be required in EPA’s Significant New Use Rules (SNURs) under TSCA. The letter also stresses describes why PPE is ineffective at controlling hazards, stating: “OSHA therefore continues to consider the use of respirators to be the least satisfactory approach to exposure control.”²

Given that all new OSHA standards for workplace chemical exposures require primary use of engineering controls, if OSHA had a Permissible Exposure Limit (PEL) for workplace exposure regulation for C.I. Pigment Violet, OSHA would require employer to implement engineering controls before considering PPE, recognizing that PPE would not provide the same level of protection as engineering controls. Of course, OSHA does not have a PEL for C.I. Pigment Violet 29, or for thousands of other chemicals. OSHA has acknowledged that its standard setting process is broken and is unable to set standards for most workplace chemicals.^{3,4} This is one of the reasons that Congress included workers as a susceptible subpopulation covered by TSCA.

According to the Draft Risk Evaluation, the SDSs cited (but not provided) by EPA recommend engineering controls. However, this EPA Draft Risk Evaluation assumes that employers at downstream processing and use sites will instead rely on PPE to protect workers (page 22):

Engineering controls for C.I. Pigment Violet 29, as stated directly in the SDS, include adequate ventilation, processing enclosure, and local exhaust ventilation or other engineering controls. Personal protective equipment (PPE) includes safety glasses with side-shields, dust goggle under certain circumstances, chemical resistant impervious gloves, and particulate respirators if needed (BASF, 2017; CPMA, 2017a; Sun Chemical, 2017). *Oral and inhalation exposures from downstream processors and users are possible; however, occupational exposures from these downstream users are likely to be limited due to the expected use of PPE* (per Safety Data Sheet for C.I. Pigment Violet 29) and poor oral absorption due to low water solubility (BASF, 2017; CPMA, 2017a; Sun Chemical, 2017). Although oral and dermal exposure are expected to be limited due to poor adsorption and PPE utilized by workers, the EPA conducted a screening-level

analysis to quantify a theoretical high-end scenario for workers, which assumes that PPE are not utilized. (emphasis added)

In addition to the unacceptability of reliance on PPE rather than engineering controls, the Draft Risk Evaluation assumes that all employers and employees will understand and follow any recommendations of the SDSs. EPA provides no evidence to support this assumption; in fact, there is extensive evidence it is incorrect in many instances.

The EPA appears to be operating under a significant misunderstanding of OSHA regulations. OSHA's Hazard Communication Standard (HCS), issued under my signature on March 26, 2012, is an informational rule. It requires employers to provide information to employees, but it does not require employers to act on that information. In other words, merely because a SDS says that engineering controls or PPE are recommended, there is no OSHA requirement for employers to follow those recommendations. This is made clear in the following passage from the preamble (page 17693) of that standard:

One comment suggested that the standard should be limited to a purpose of international communication so as not to trigger hazard assessments under other OSHA standards that address respiratory protection, personal protective equipment, or process safety management. There were several other comments that indicated that new assessments would have to be done for these standards. Arguments were made that this would lead to extensive additional costs for new engineering controls, respirators, or other personal protective equipment.

As discussed above, there is no identified link to these other standards in the stated purpose of the HCS either currently or with the proposed modifications in the NPRM. While the current HCS and this final standard require the provision of information on recommended control measures, including respiratory protection, personal protective equipment, and engineering controls, *there is no requirement for employers to implement the recommended controls*. An employer should use all available information when designing an appropriate protective program, but *a recommendation on a safety data sheet by itself would not trigger the need to implement new controls*.⁵ (Emphases added)

The purely informational nature of the HCS is confirmed in the two documents that guide OSHA's enforcement activities: OSHA's Inspection Procedures for the Hazard Communication Standard (HCS 2012) directive⁶ and the agency's Field Operations Manual.⁷

In addition, understanding the information in an SDS is a prerequisite for applying its recommendations. A related incorrect assumption in the Draft Risk Evaluation is that workers and employers (especially small ones) will easily understand the SDS. In fact, both workers and small employers have a great deal of trouble understanding SDSs; one study found that, on average "the information on the MSDSs was found to be about one-third incomprehensible."⁸

It is also important to note that employers often ignore not only the recommendations of SDSs but basic, common-sense safety rules. **This is tragically demonstrated by the two workers killed at manufacturing facilities of Sun Chemicals, which appears to be the sole US manufacturer of C.I. Pigment Violet 29. A temporary worker was asphyxiated in November 2015 at Sun Chemical's South Carolina plant.⁹ In November 2011, a worker in a different Sun Chemical facility was crushed by a bag of color toner.¹⁰ Both of these deaths resulted in citations by**

OSHA for violating regulations. It is therefore imperative that EPA be clear in its Risk Evaluations as to the hazards and risks from which workers need to be provided with an adequate level of protection.

Incorrect Assumptions about the Accuracy and Completeness of SDSs

It is also important to note that the EPA Draft Risk Evaluation assumes that SDSs are complete and accurate. While it is not possible to judge the specific SDSs used in the risk evaluation because EPA has not shared them, it is widely recognized that SDSs often contain inaccuracies and are often incomplete. There are many studies that have reached these conclusions. I am quoting one here because it is a review of 24 studies of SDSs (referred to as MSDSs in the article). This review concluded:

Despite the fact that these studies varied in methodology and spanned a period of more than 15 years, a number of common themes emerged regarding inaccuracies, incompleteness, incomprehensibility and overall low use of MSDSs. The results of the literature review suggest that there are serious problems with the use of MSDSs as hazard communication tools¹¹

Employers are required to make a good faith effort to obtain accurate and complete SDSs from manufacturers or distributors, and they must rely on those parties got this. Under OSHA enforcement policy, employers assume no responsibility for the content and accuracy of the SDS provided to them by the manufacturer, importer or distributor.⁶ Most employers are unlikely to be able to identify poor quality SDSs, but are likely to use them as the primary source of information about the chemical in question.

It is important to note that OSHA has little ability to require manufacturers or distributors to correct inaccurate or incomplete SDSs. First, OSHA Compliance Safety and Health Officers (CSHOs) rarely have the time, resources or expertise to evaluate all SDSs in the course of a workplace inspection. In spite of this, if it comes to OSHA's attention that a specific SDS is inaccurate or incomplete, federal OSHA cannot cite the manufacturer or distributor if they are located in one of the 21 states (including California) in which federal OSHA does not have jurisdiction, or if they are located overseas. And if OSHA attempts to cite a manufacturer or distributor located in OSHA's jurisdiction, the Agency must prove the SDS is deficient. As a result, OSHA has done this, at most, in a small handful of cases.

Unjustified Conclusions about Exposure Levels

In the Draft Risk Evaluation, EPA reaches a conclusion about worker exposure that cannot be justified. The Draft provides little evidence to judge its first assumptions about exposure levels in manufacturing plants. The Agency then compounds the problem by going further to assert the absolutely unfounded conclusion that (page 21):

Because per site volumes handled by downstream users are likely to be much less than the manufacturer (i.e., less than 5 percent each), it is expected that...air emissions will be proportionally lower.

There is absolutely no basis for this statement. At OSHA, there were many, many instances where exposures in downstream users of a chemical or product were substantially higher than exposures in manufacturing facilities.

Conclusion

It is clear that the Draft Risk Evaluation is filled with unsupported or incorrect assumptions and conclusions regarding worker exposures and associated protective measures. As a result, the Agency has failed to provide adequate evidence to meet the requirements of TSCA that a risk evaluation “determine whether at chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of cost or other non-risk 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.” TSCA section 3(12) defines the term “potentially exposed or susceptible subpopulation” as a group of individuals within the general population identified by the Administrator who “may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, *workers*, or the elderly.” (Emphasis added)

In this case, workers are the relevant potentially exposed or susceptible subpopulation, and EPA has not provided adequate evidence that it has made an accurate determination as required by TSCA.

I respectfully request the Draft Risk Evaluation be withdrawn and modified to correct the mistakes and incorrect assumptions I have identified. As part of addressing these corrections, I request that EPA post full copies of all 24 of those studies that were used to prepare this document but were not available for public review.

Thank you for your consideration.



David Michaels, PhD, MPH

¹ http://www2.basf.us/additives/pdfs/Paliogen_Redviolet_K5011.pdf

² <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0041>

³ <https://www.osha.gov/news/speeches/10092014>

⁴ <https://www.osha.gov/laws-regs/federalregister/2014-10-10>

⁵ https://www.osha.gov/FedReg_oseha_pdf/FED20120326.pdf

⁶ https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-079.pdf

⁷ https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-00-160.pdf

⁸ P Kolp, B Sattler, M Blayney, T Sherwood. Comprehensibility of material safety data sheets. *American Journal of Industrial Medicine*. 1993;23(1):135-141.

⁹ https://www.osha.gov/pls/imis/establishment.inspection_detail?id=1109252.015

¹⁰ https://www.osha.gov/pls/imis/establishment.inspection_detail?id=315387126

¹¹ Nicol A, Hurrell AC, Wahyuni D, McDowall W, Chu W. Accuracy, comprehensibility, and use of material safety data sheets: A review. *American Journal of Industrial Medicine*. 2008;51(11):861-876.