



INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE & AGRICULTURAL IMPLEMENT WORKERS OF AMERICA – UAW

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December 17, 2020

Alexandra Dapolito Dunn  
Assistant Administrator  
Office of Chemical Safety and Pollution Prevention  
Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Re: Comments of the International Union, UAW on the Draft Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f]diisoquinoline-1,3,8,10(2H,9H)-tetrone) (Docket Number EPA-HQ-OPPT-2018-0604 FRL-10017-38)

Submitted by Brett Fox, UAW Health and Safety Director at:

<https://www.federalregister.gov/documents/2020/11/23/2020-25823/ci-pigment-violet-29-revised-draft-toxic-substances-control-act-tsca-risk-evaluation-notice-of>

Assistant Administrator Dapolito Dunn:

The International Union, UAW represents one million active and retired workers, including auto workers, and others who are potentially exposed to C.I. Pigment Violet 29 (PV 29) in automobile paint. We are grateful for the opportunity to comment on this draft risk evaluation. EPA's estimates of exposure and risk are not based on sufficient evidence. They are likely to be underestimations for occupational users and they do not support the finding of "No Unreasonable Risk" for occupational non-users. If allowed to stand, this unsupported finding would effectively end federal and state regulation of this substance for occupational non-users under most conditions of use.

We again urge the EPA to withdraw its draft risk evaluation, commit to the data collection and analysis that is needed to fully evaluate PV29, and re-issue yet another revised risk evaluation for public review and comment.

## **EPA's Finding of "No Unreasonable Risk" among many Categories of "Occupational Non-Users" is Not Supported by Scientific Evidence**

EPA found that there were no unreasonable risks of lung overload for so-called "occupational non-users" (ONUs) in the following conditions of use (COU):

- Domestic Manufacture
- Manufacture – Import
- Incorporation into formulation, mixture or reaction products in paints and coatings
- Incorporation into formulation, mixture or reaction products in plastic and rubber products
- Intermediate in the creation or adjustment of color of other perylene pigments
- Recycling
- Automobile plastics
- Industrial carpeting
- Paints and coatings – Automobile (OEM and refinishing)
- Paints and coatings – Coatings and basecoats
- Merchant ink

EPA defines ONUs as "workers who do not directly handle PV29 but perform work in an area where PV29 is present." Unfortunately, EPA has failed to provide the evidence required to support the findings of "no unreasonable risk" for occupational non-users in all these COUs. To estimate the exposures of ONUs, EPA relies on samples of four operators. Each of the four were sampled for less than an hour. In all four cases, the amount of PV29 was below the limit of quantification (LOQ) of the method. This is not necessarily because exposures were low. It is quite possibly due to the fact that the sampling time was so short, especially for the purpose of estimating an 8-hour time weighted average. On the basis of full shift exposure estimates, based on four samples, none of which collected enough PV29 to quantify, EPA concludes that there is no ONU in the United States subject to unreasonable risk. This extraordinarily insufficient data cannot possibly support such a conclusion. In addition to the fact that the sampling time is unacceptably short, four samples are unacceptably few. These data are entirely inadequate by industrial hygiene criteria<sup>1</sup>.

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<sup>1</sup> European Chemicals Bureau (1996). *Technical Guidance document in support of Commission Directive 93/87/EEC on risk assessment for new notified substances and Commission Regulation (EC) 1488/94 on risk assessment for existing chemicals*. Ispra: European Chemicals Bureau.

European Committee on Standardization (CEN, 1995). *Workplace Atmospheres. Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy*. EN689, Brussels.

Rappaport SM, Lyles RH, and Kupper LL. (1995). An exposure assessment strategy accounting for within- and between- worker sources of variability. *Annals of Occupational Hygiene* 39: 469-95.

Cited in

Tielemans E, Marquart H, De Cock J, Groenewold M, & Van Hemmen J. (2002). A proposal for evaluation of exposure data. *Annals of Occupational Hygiene*, 46(3), 287-297.

On the basis of these four samples, EPA concludes that the exposure of ONUs is always less than the exposures of workers who directly handle PV29. While this may be true of many ONUs, it is also likely that workers engaged in maintenance and repair of machines that process PV29 or cleaning of containers used for PV29 have peak exposures that exceed those of production workers who work directly with PV29. EPA failed to obtain, examine, or present data related to the occupational exposures of workers engaged in maintenance cleaning or repair. One example of elevated exposures among workers engaged in these activities can be found in a study of urinary Bisphenol A as a marker of exposure. This study found that the geometric mean level of BPA in the urine of maintenance workers was 156 µg/g. This was higher than such occupational users as flaker operators and kettle operators<sup>2</sup>. These data show the possibility that maintenance, repair and cleaning workers have higher levels of exposure than occupational users. EPA failed to collect or examine any data to address this question.

EPA's failure to examine the exposures of maintenance repair and cleaning workers and its reliance on an unacceptably small number of samples with unacceptably short sampling times means that it has failed to produce evidence to justify its conclusions of "no unreasonable risk" for a wide variety of ONUs. These conclusions cannot be sustained.

Moreover, EPA assumed, in the complete absence of data, that dust concentrations in industries that process PV29 are no higher than the highest reported dust concentrations in manufacturing at Sun Chemical. EPA estimated the highest full-shift exposure to occupational users at Sun Chemical at 0.37 mg/m<sup>3</sup> and reported that workers at Sun Chemical handle PV29 at nearly 100% concentration. However, sampling of repair technicians engaged in orbital sanding of automobile paint<sup>3</sup> has found total dust concentrations as high as 12 mg/m<sup>3</sup>. Under this condition of use exposures could exceed those in manufacturing if the concentration of PV 29 in the paint exceeds 3.08%. EPA has no valid basis for concluding that processing exposures will not exceed manufacturing exposures.

### **Despite finding Unreasonable Risks for "Occupational Users", EPA Underestimated the Risks**

EPA assumed the use of respirators with an assigned protection factor (APF) of 10 for the following conditions of use: Domestic Manufacturing, Import, Processing as a reactant, Paints and Coatings, Plastic and Rubber products, Recycling, and Disposal. The means that EPA assumed that effective exposures were approximately one tenth of those measured and that risks were correspondingly lower. This assumption is supported only by a report from Sun Chemical that workers wear "dust masks" during manufacturing activities. EPA does not report whether the wearing of "dust masks" is voluntary or mandatory. Nor does EPA report how it determined that it was appropriate to assign a protection factor of 10 to these "dust masks." A search for "dust

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<sup>2</sup> Hines, C.J., Jackson, M.V., Deddens, J.A., Clark, J.C., Ye, X., Christianson, A.L., Meadows, J.W. and Calafat, A.M., 2017. Urinary bisphenol A (BPA) concentrations among workers in industries that manufacture and use BPA in the USA. *Annals of work exposures and health*, 61(2), pp.164-182.

<sup>3</sup> Enander, R. T., Cohen, H. J., Gute, D. M., Brown, L. C., Desmaris, A. M. C., & Missaghian, R. (2004). Lead and methylene chloride exposures among automotive repair technicians. *Journal of Occupational and Environmental Hygiene*, 1(2), 119-125.

mask<sup>4</sup>” on the internet includes results that are clearly not filtering facepiece respirators and should not receive an assigned protection factor of 10. Moreover, with the current PPE shortage in health care,<sup>5</sup> it is quite likely that “dust masks” used in manufacturing are not filtering facepiece respirators, even if they were in the past. This is an excellent illustration of why risk assessment needs to be separated from risk management, as set forth in the National Research Council “Red Book.”<sup>6</sup> Even if the assumption about PPE had been correct prior to the pandemic, it would still have been inappropriate to estimate risk on the basis of that assumption. PPE is a risk management tool. The pandemic made that particular risk management tool less available. An appropriate risk evaluation would estimate risk independent of the availability of a particular risk management tool. This would prevent underestimating the risk based on the assumed use of a risk management tool that a worldwide pandemic has made unavailable.

## Conclusion

EPA proposes a “no unreasonable risk” finding for ONUs’ exposure to PV29 in a variety of conditions of use. If finalized as proposed, this determination would effectively put an end to both federal and state regulation of this substance for ONUs under the conditions of use enumerated above. There is no scientific basis for this proposed finding. EPA has relied on the unsubstantiated assumption that exposures in processing industries are always lower than in manufacturing and that all ONUs, including those engaged in maintenance, repair and cleaning have lower exposures than occupational users. Although EPA found unreasonable risks for most “occupational users,” it nevertheless systematically underestimated those risks by assuming, without evidence, that all such workers use filtering facepiece respirators with an assigned protection factor of 10. This assumption is questionable in normal times based on the limited evidence EPA relied on. In a pandemic, during which there are not enough such respirators for health care, the assumption that they would be available in manufacturing is utter nonsense. This highlights the importance of separating risk evaluation from risk management. Even if EPA’s risk management assumptions were correct for non-pandemic times (which they are not), they would be inapplicable to pandemic times. For that reason, risk management assumptions should not be “baked in” to risk evaluations. EPA should withdraw its draft risk evaluation, commit to the data collection and analysis that is needed to fully evaluate PV29, and re-issue yet another revised risk evaluation for public review and comment.

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<sup>4</sup> [https://www.industrialsafetygear.com/Box-Of-50-Nuisance-Dust-Masks\\_p\\_7747.html?utm\\_source=bing&utm\\_medium=cpc&utm\\_campaign=BPA%20-%20General%20-%20Miscellaneous&utm\\_term=4581115203187327&utm\\_content=BPA%20General%20-%20Miscellaneous%7CPyramex%7C0-25%7CC%3A50](https://www.industrialsafetygear.com/Box-Of-50-Nuisance-Dust-Masks_p_7747.html?utm_source=bing&utm_medium=cpc&utm_campaign=BPA%20-%20General%20-%20Miscellaneous&utm_term=4581115203187327&utm_content=BPA%20General%20-%20Miscellaneous%7CPyramex%7C0-25%7CC%3A50) (accessed December 15, 2020).

<sup>5</sup> <https://www.medscape.com/viewarticle/942064>

<sup>6</sup> National Research Council. (1983). *Risk assessment in the federal government: managing the process*. National Academies Press.