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Comments of the International Union, UAW
on the
Draft Risk Evaluation for 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)

January 14, 2019

The International Union, UAW represents one million active and retired workers, including auto workers, and others who are potentially exposed to PV 29. We are grateful for the opportunity to comment on this draft risk evaluation. EPA proposes to make a risk determination that "C.I. Pigment Violet 29 does not present an unreasonable risk of injury to human health or the environment… including no unreasonable risk to potentially exposed and susceptible subpopulations identified as relevant, under the conditions of use…" If finalized as proposed, this risk determination would constitute an order per TSCA section 6(i)(1) that this chemical does not present an unreasonable risk. Such an order would effectively put an end to both federal and state regulation of this substance. EPA must withdraw its draft risk evaluation, commit to the data collection and analysis that is needed to fully evaluate C.I. Pigment Violet 29 (PV 29), and re-issue a revised risk evaluation, along with all of the underlying health and safety studies, for public review and comment.

The UAW has identified several reasons for which this proposed finding is scientifically unsound and should be withdrawn:

1. There are no chronic exposure studies of PV 29. Such studies are crucial to the research of many local and systemic endpoints, such as cancer and target organ toxicity. This substance has not been adequately examined scientifically. It would be premature to issue a "no unreasonable risk" determination before such studies have been done.

2. The acute inhalation studies that EPA relies on to find that "Low hazard was reported" were considered by the European Chemical Agency (ECHA) to be "insufficient for non-volatile substances." EPA ignored studies of related substances that ECHA concluded were applicable to PV 29. In these studies, animals exhibited clinical signs that included accelerated respiration and pulmonary respiration sounds. One of the test animals died.

3. EPA relies on a single personal communication for its occupational exposure data. This does not meet the scientific standards of industrial hygiene.

4. EPA asserts without evidence that downstream workers will have lower exposure than manufacturing workers. It relies on the assumption that, despite inadequate guidance in the safety data sheets (SDS), all downstream employers will successfully protect their employees using the least effective method, namely personal protective equipment (PPE).

EPA Relies on Flawed Studies

In its *Problem Formulation of the Risk Evaluation for C.I. Pigment Violet 29*,[1] EPA acknowledged "There were no repeated-dose toxicity studies found for C.I. Pigment Violet 29." Such studies are crucial to the research of chronic effects including many local and systemic endpoints, such as cancer and target organ toxicity. In the absence of such studies, it is scientifically unsound to issue a risk determination that a substance does not present an unreasonable risk. The risk posed by this substance has not yet been adequately examined scientifically. Such a determination would be premature.

In support of its "no unreasonable risk" determination, EPA states that "Low hazard was reported in human health testing via all routes of exposure (oral, dermal and inhalation), nor were dermal or eye irritation effects reported." In coming to this conclusion, EPA treated the available data very differently from the way it was treated by the ECHA, from which EPA obtained the data. According to ECHA,[2]

> The test article [PV 29] belongs to the "perylene based organic pigments" category… According to the category approach, missing toxicity endpoints can be addressed with data available for other category members…
>
> Inhalation toxicity
>
> Regarding inhalation, ***only unreliable data is available for the test article.*** Two inhalation risk tests (BASF 77/360, 1978 and BASF XXV-454, 1976)… were performed with the test article… In the first test…[a]verage concentration of the test article in the atmosphere was calculated at 0.31 mg/l… In the second… [a]verage concentration of substance in the atmosphere as stated in the report was 14.74 mg/l. ***However, since this test design is insufficient for non-volatile substances, these tests are disregarded…***
>
> Reliable data is available for other category members… Except for one study ***with a single case of mortality*** all animals survived the procedures. ***The observed clinical signs included accelerated respiration, pulmonary respiration sounds*****,** squatting posture, piloerection, flight behavior and

[1] USEPA (2018). *Problem Formulation of the 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), CASRN: 81-33-4*. EPA Document# 740-R1-7021: Office of Chemical Safety and Pollution Prevention.

[2] https://echa.europa.eu/registration-dossier/-/registered-dossier/10330/7/3/1 (accessed 1/3/2019)

smeared fur…

…The data obtained with the category members is used to define an LC_{50} value in rats for the test article after inhalation of above 5000 mg/m^3. [Emphasis added]

Since EPA relies heavily on ECHA for studies of PV 29, EPA owes the public an explanation as to why it differs with the European agency as to which studies to use. According to Appendix D (p.41), EPA relied on a pair of inhalation studies (BASF, 1978a and BASF, 1975a) in which the exposure concentrations were 0.31 mg/l and 14.74 mg/l. As indicated above, ECHA declined to rely on these studies because "this test design is insufficient for non-volatile substances." EPA chose to ignore tests of related perylene based organic pigments that ECHA relied on. In one of these studies, unlike in those that EPA relied on, one of the animals died. In addition, animals experienced respiratory difficulty at 5.2 mg/l, which appears to be the only nonzero exposure level in this study. It is possible that such respiratory effects may occur well below that concentration, but this does not appear to have been tested in animals or studied in humans. It is scientifically unsound for EPA to make a finding of "no unreasonable risk" on such limited data and to offer no explanation as to why it has made different choices from ECHA as to which studies to accept.

EPA's Risk Analysis Relies on Scientifically Unacceptable Exposure Information

EPA states that it identified no risks associated with this substance on the basis of a screening-level analysis. To do this, EPA compared a No Observed Adverse Effect Level (NOAEL) in Wistar rats of 1000 mg/kg/day taken from a reproductive study[3] to what it describes as a worst-case exposure scenario for workers at a manufacturing site operating without personal protective equipment (PPE). EPA finds that its "worst-case" exposure is almost 15,000 times less than the dose resulting from the NOAEL. This analysis is fundamentally flawed for two reasons. First, as indicated above, in the absence of repeated dose studies, it is impossible to know whether 1000 mg/kg/day is a true NOAEL. It is possible that the true NOAEL is an order of magnitude lower or more. Until the studies are done, it is premature to make a finding of "no unreasonable risk."

Second, the data on which the "worst-case exposure scenario" is based are even less reliable. EPA states "The sole manufacturer of C.I. Pigment Violet 29 reported an approximate maximum workplace air concentration of 0.5 mg/m^3 would be expected over a 12-hour shift (Mott, 2017a). It is not clear whether the monitoring data were for C.I. Pigment Violet 29 or for total dust. If the data were for total dust, the actual air concentration of C.I. Pigment Violet 29 is likely to be lower than 0.5 mg/m^3 (Mott, 2017a)." EPA admits that it does not know whether the monitoring data were for total dust or for the target material. Moreover, the citation "Mott, 2017a," is as follows: "Personal communication between Dr. Robert C. Mott (Sun Chemical Corporation) and Alie Muneer (EPA) regarding exposure questions [Personal Communication]." EPA

[3] Stark, D; Treumann, S; van Ravenzwaay, B (2013). *Reproduction/developmental toxicity screening test in Wistar rats oral administration (gavage).* Report Number 80R0223/11C162. Germany: BASF SE.

bases its “worst-case exposure scenario” solely on a personal communication, relying on no actual data to conclude that this is the highest level to which workers could possibly be exposed.

In the profession of Industrial Hygiene, there are well-developed criteria for the use of exposure data in risk assessment. Much more is required than a single number. While there is not complete consensus as to the minimum number of samples necessary to identify an approximate maximum concentration, it is at least 12 and it may be 20 or more.[4] Despite this, EPA has simply reported a single number based on a personal communication. There is no indication that EPA has seen the sampling data, knows what they are, knows how many samples have been taken, or knows anything else about the data. Moreover, the sampling data should be available for public review so that commenters can provide their own interpretations to the docket. The public should not have to rely on the judgment of the manufacturer and the Agency that this is indeed the maximum exposure level.

In Industrial Hygiene, for data to be considered moderate quality, the following information must be available about the context in which the sampling was done[5]:

[4] 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.

[5] Rajan, B., Alesbury, R., Carton, B., Gerin, M., Litske, H., Marquart, H., Olsen , E., Scheffers, T., Stamm, R. & Woldbaek, T. (1997). European proposal for core information for the storage and exchange of workplace exposure measurements on chemical agents. Applied Occupational and Environmental Hygiene, 12(1), 31-39.
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.

- The names of the chemical agents sampled
- The economic activity and size of the premises
- The processes that were sampled
- The occupations and tasks of the workers sampled
- The exposure control measures used
- The measurement strategy
- The dates of the samples
- The devices used to do the sampling (e.g. whether the devices were instant read or required lab analysis)
- Whether the samples were breathing zone or environmental samples (should be breathing zone for risk assessment)
- Duration of sampling (instantaneous, 15 min short term exposure limit sample, 8-hour shift, 12-hour shift, etc.)
- Analytical methods used
- Concentration measured for each sample (not just a report of the "highest")
- Units of measurement
- Sample Status

For data to be considered high quality, all of the above information would have to be available and the following data would need to be available as well[5]:

- Name and Address of premises
- Departments and work areas that were sampled
- The names and/or identifiers of the products containing the chemical agents sampled
- Exposure patterns
- RPE used
- Confinement
- Sample ID for each sample
- Exact sampling times
- Duration of exposure (Is it the same as the duration of sampling? Is it uniform throughout the shift? Are there periods of the shift with minimal or no exposure? Are certain tasks associated with peak exposures?

The Mott communication as reported by EPA fails to meet the minimal requirements for poor quality data, which are as follows[6]:

- Occupations and tasks of the workers sampled
- Name of the chemical agent sampled (EPA doesn't even know whether it is PV 29 or total dust)
- The year in which each sample was taken (precise dates would be better)
- Whether the samples were breathing zone or environmental samples (should be breathing zone for risk assessment)
- Duration of sampling (instantaneous, 15 min short term exposure limit sample, 8-hour shift, 12-hour shift, etc.)
- Concentration measured for each sample (not just a report of the "highest")
- Units of measurement
- Sample Status

Since the Mott communication fails to meet the criteria for poor quality, it would have to be classified as *unacceptable*[6]. It cannot be used to support a finding of "no unreasonable risk."

EPA Has No Evidence that Downstream Workers Will Have Lower Exposures

EPA makes a blanket assertion that all other exposures "are likely to be less than these worst-case scenarios." EPA bases this conclusion on several arguments. First, EPA argues "Oral ingestion is not a relevant pathway for workers manufacturing C.I. Pigment Violet 29 since there is no foreseeable route of exposure. Standard workplace practices prohibit eating and smoking in manufacturing facilities." This blanket rejection of the oral route of exposure is simply not supported by science. It has been estimated that approximately one in six workers may be involved in tasks in which inadvertent ingestion exposure could contribute to their total body burden[7].

EPA goes on to say "[O]ccupational exposures from… downstream users are likely to be limited due to the expected use of PPE (per Safety Data Sheet for C.I. Pigment Violet 29)…" In support of this assertion EPA quotes the manufacturers' safety data sheet (SDS), which states "Personal protective equipment (PPE) includes safety glasses with side-shields, dust goggle under certain circumstances, chemical resistant impervious gloves, and particulate respirators if needed…" There are several problems with this. First the instructions in the SDS are inadequate. The downstream user is not informed under what circumstances a dust goggle may be needed, nor is the user informed as to what kind of glove will be protective or when a particulate respirator is "needed." This means that, even in the best case, where every downstream user makes an earnest effort to provide the correct PPE, they do not have enough information to know what the correct PPE is.

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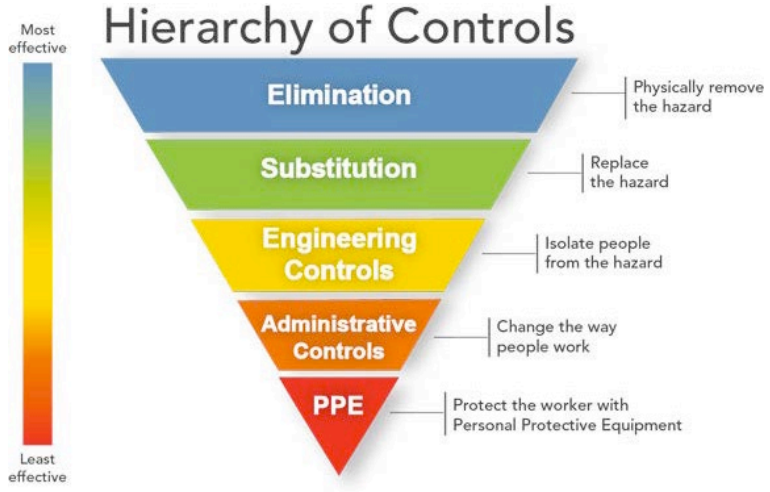
[6] *Ibid.*

[7] Cherrie, J. W., Semple, S., Christopher, Y., Saleem, A., Hughson, G. W., & Philips, A. (2006). How important is inadvertent ingestion of hazardous substances at work? The Annals of occupational hygiene, 50(7), 693-704.

In relying on an assumption of universal voluntary[8] use of PPE to make its finding of "no unreasonable risk," EPA ignores the hierarchy of controls entirely. The hierarchy is a core component of standards issued by the U.S. Department of Labor – Occupational Safety and Health Administration (USDOL – OSHA). The hierarchy requires employers to eliminate, prevent and/or control hazards based upon the following preferred order of controls:

A) First: Elimination;
B) Then: Substitution of less hazardous materials, processes, operations or equipment;
C) Then: Engineering controls;
D) Then: Administrative controls; and
E) As a last resort: Personal Protective Equipment ("PPE")[9].

OSHA has relied upon the hierarchy of controls in every health standard it has issued[10]. the Centers for Disease Control & Prevention, National Institute for Occupational Safety & Health (CDC-NIOSH) depicts the hierarchy of controls with this graphic, which shows the significantly increased effectiveness of controls other than PPE[11]:



[8] Since EPA does not propose in the document to require PPE, it is must be relying on universal voluntary PPE use.

[9] Manuele FA (2006). ANSI/AIHA Z10-2005: The New Benchmark for Safety Management Systems. *Professional Safety* 25:30. http://www.coshnetwork.org/sites/default/files/Z10%20New%20Benchmark%20for%20Health%20and%20Safety%20Systems%20by%20Fred%20Manuele.pdf

[10] Cf. 29 C.F.R. § 1926.55 (to prevent employee exposure to inhalation, ingestion, skin absorption or contact with substances above safe levels, "engineering controls must first be implemented whenever feasible; when such controls are not feasible to achieve full compliance, protective equipment or other protective measures shall be used….."); 29 C.F.R. § 1910.134(a)(1) (to control occupational disease due to contaminated air, "the primary objective shall be to prevent atmospheric contamination. This shall be accomplished as far as feasible by accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials). When effective engineering controls are not feasible, or while they are being instituted, appropriate respirators shall be used"); 29 C.F.R. § 1910.1025(e) (where employees are exposed to lead over permissible levels, "the employer shall implement engineering and work practice controls (including administrative controls) to reduce and maintain employee exposure to lead").

[11] Hierarchy of Controls, NIOSH (last updated July 18, 2016), https://www.cdc.gov/niosh/topics/hierarchy/.

EPA's finding of "no unreasonable risk" rests on the assumption that all employers will successfully control exposure by voluntarily applying the least effect exposure control method, namely PPE. From this EPA concludes that no exposures in downstream users will exceed those in manufacturing. This is not scientifically justifiable.

Sampling of repair technicians engaged in orbital sanding of automobile paint[12] has found total dust concentrations as high as 12 mg/m^3. Since it is unknown whether or not the samples reported in the Mott communication were total dust, these downstream workers may have exposures up to 24 times as high as the manufacturing workers. If we assume that the Mott communication referred to PV 29 only, these downstream exposures could exceed those in manufacturing if the concentration of PV 29 in the paint exceeds 4.2%. EPA has no valid basis for concluding that downstream exposures will not exceed manufacturing exposures.

Conclusion

EPA proposes to make a risk determination that "C.I. Pigment Violet 29 does not present an unreasonable risk of injury to human health or the environment…" If finalized as proposed, this risk determination would effectively put an end to both federal and state regulation of this substance.

EPA's proposed finding cannot be justified scientifically for the following reasons:

1. There are no chronic exposure studies of PV 29. Such studies are crucial to the research of many local and systemic endpoints, such as cancer and target organ toxicity. This substance has not been adequately examined scientifically. It would be scientifically unsound to issue a "no unreasonable risk" determination before such studies have been done.
2. The acute inhalation studies that EPA relies on to find that "Low hazard was reported" were considered by ECHA to be "insufficient for non-volatile substances." EPA ignored studies of related substances that ECHA concluded were applicable to PV 29. In these studies, animals exhibited clinical signs that included accelerated respiration and pulmonary respiration sounds. One of the test animals died.

3. EPA relies on a single personal communication for its occupational exposure data. This does not meet the scientific standards of industrial hygiene.

4. EPA asserts without evidence that downstream workers will have lower exposure than manufacturing workers. It relies on the assumption that, despite inadequate guidance in the SDS, all downstream employers will successfully protect their employees using the least effective method, namely personal protective equipment.

[12] 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.

There is no scientific basis for EPA's proposed "no unreasonable risk" finding. EPA musts withdraw its draft risk evaluation, commit to the data collection and analysis that is needed to fully evaluate PV 29, and re-issue a revised risk evaluation, along with all of the underlying health and safety studies, for public review and comment.

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