



# AmericanCoatings

ASSOCIATION<sup>SM</sup>

April 29, 2025

Carolyn Mottley,  
Existing Chemicals Risk Management Division (7404M)  
Office of Pollution Prevention and Toxics  
Environmental Protection Agency  
1200 Pennsylvania Ave. NW  
Washington, DC 20460-0001

*Re: EPA Proposed Risk Management Rule for PV29  
EPA-HQ-OPPT-2021-0277  
Submitted online at: [www.regulations.gov](http://www.regulations.gov)*

Dear Ms. Mottley:

The American Coatings Association (ACA)<sup>1</sup> appreciates the opportunity to submit information and comments to assist EPA with developing a risk mitigation strategy for C.I. Pigment Violet 29 (PV29), under the *Frank R. Lautenberg Chemical Safety for the 21st Century Act* (“Lautenberg Act”). We are committed to working with EPA to help ensure effective risk mitigation strategies under the *Toxic Substances Control Act* (TSCA).

The Association’s membership represents 90% of the paint and coatings industry, including downstream users (or processors) of chemicals, as well as chemical manufacturers. Our membership includes companies that manufacture paint, coatings, sealants and adhesives, whose manufacturing processes or products may be affected by the outcome of EPA’s rulemaking for PV-29. ACA and its members have submitted comments and met with EPA at various stages of the EPA risk evaluation and during drafting of the risk mitigation rule. ACA staff also served as a small entity representative advising the SBAR (Small Business Advocacy Review) panel. We appreciate the opportunity to continue advising EPA regarding risk mitigation.

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<sup>1</sup> ACA is a voluntary, non-profit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA serves as an advocate and ally for members on legislative, regulatory and judicial issues. ACA’s membership represents over 90 percent of the total domestic production of paints and coatings in the country.

ACA appreciates EPA's willingness to interact with stakeholders during this process. ACA understands that implementation of the *Lautenberg Act* presents several challenges, and we commend EPA on the solutions it has offered thus far. We are optimistic that through continued involvement with the public and stakeholder community, EPA will successfully implement a stronger federal chemicals management program for years to come. ACA and its members respectfully submit the following comment:

## **I. Introduction**

Although ACA strongly supports EPA's findings related to lack of bioavailability of PV29 in formulated products, ACA notes that EPA's primary risk mitigation proposal and its proposed regulatory alternative are not clearly justified by the risk evaluation and therefore impose an undue burden on industry, beyond the limitation established in TSCA § 6(a). Implementation of proposed risk mitigation strategies is hindered by the lack of viable exposure or dust level monitoring methods to measure against an accurately identified exposure value. Because of the broad and unfounded assumptions in the underlying risk evaluation, EPA has not established clear use or handling practices affecting exposure to prescribe risk mitigation measures, as required under TSCA Section 6(a), "to the extent necessary," but not in excess, to abate the identified risk. The risk evaluation does not provide enough information to justify the proposed risk mitigation requirements or its regulatory alternative.

Because these problems are rooted in the underlying risk evaluation, ACA strongly recommends that EPA revise its risk evaluation to more accurately assess risk with an accurate exposure value, if needed, while considering current handling and practices in its exposure evaluation. This is needed to provide EPA's risk mitigation team with enough information to develop a viable risk mitigation strategy. ACA further provides comments detailing deficiencies in the risk mitigation proposal and encourages EPA to reassess the regulatory alternative and possible options for risk mitigation.

Including this *Introduction*, ACA's comment details these issues through the following sections:

- I. Introduction
- II. EPA should revise the underlying risk evaluation before proceeding to risk mitigation
- III. EPA should recognize minimal exposure potential of nanoscale dust particles
- IV. EPA's risk evaluation supports current requirements classifying PV29 as a non-hazardous nuisance dust
- V. OSHA's respirator protection standard provides comprehensive safety requirements
- VI. ACA supports EPA's conclusion that PV29 particulates are not bioavailable and therefore downstream products should not be regulated
- VII. Risk Mitigation Strategies

VIII. Responses to Specific EPA Requests for Comment

IX. Conclusion

## **II. EPA should revise the underlying risk evaluation before proceeding to risk mitigation**

ACA strongly recommends revising the underlying risk evaluation before proceeding to risk mitigation. In its final risk evaluation published in January 2021, EPA issued findings of unreasonable risk for exposures in the workplace for several conditions of use affecting ACA members, including:

- Processing – Incorporation into formulation, mixture or reaction products in paints and coatings.
- Industrial / Commercial Use – Paints and Coatings – Automobile (OEM and refinishing).
- Industrial / Commercial Use – Paints and Coatings – Coatings and basecoats.<sup>2</sup>

For all of the conditions of use, EPA finds an unreasonable risk to workers for non-cancer effects (alveolar hyperplasia, inflammatory and morphological changes in the lungs) from chronic inhalation exposures at the high-end, even when assuming use of personal protective equipment (PPE), including the use of PF-10 respirators. EPA also found unreasonable risk of non-cancer effects from inhalation for occupational non-users, that is, by-standers in the workplace. EPA notes that “Inhalation exposures for workers were assessed using the maximum concentration of particles measured at the C.I. Pigment Violet 29 manufacturing site as a high-end exposure estimate.”<sup>3</sup>

The final risk evaluation includes modifications to prior drafts based on EPA’s interpretation of the PV29 manufacturer’s data submitted pursuant to a TSCA Section 4 test order. EPA explains that the manufacturer provided data for short durations of time that did not reach the limit of quantitation. That is, the manufacturer provided exposure monitoring data for actual shift times. Exposure during these shifts did not reach threshold levels for detection by analytical equipment. EPA explains that the manufacturer should have sampled greater volumes of air with greater air flow through analytical equipment to measure trace amounts at issue.<sup>4</sup>

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<sup>2</sup> U.S. Environmental Protection Agency, Risk Evaluation for C.I. Pigment Violet 29 CASRN: 81-33-4 (January 2021) at page 88-90.

<sup>3</sup> U.S. Environmental Protection Agency, Risk Evaluation for C.I. Pigment Violet 29 CASRN: 81-33-4 (January 2021) at page 91-96. (See p. 91, et. seq., Draft Risk Assessment).

<sup>4</sup> U.S. Environmental Protection Agency, 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 (January 2021) at page 53.

EPA conducted further evaluation, with two significant assumptions:

- 1) EPA assumed worker exposure will be at ½ the quantitation limit, extrapolated over 10.5 hours, the total time of one production shift.
- 2) EPA assumed particle size distribution of respirable dust at .043 to 10.4 micrometers, thereby including exposure to nanoscale particles at 0-0.1 micrometers.<sup>5</sup>

While this final risk evaluation was in the proposal stage, the Color Pigment Manufacturer's Association (CPMA) provided a detailed analysis of the limitations of EPA's approach in comments filed in December 2020. ACA filed a comment letter in support of CPMA's analysis.

ACA requests that EPA incorporate an understanding of these limitations when developing a risk mitigation approach, so as not impose unnecessary risk mitigation requirements. Notably, TSCA Section 6(a) requires EPA issue risk mitigation rules *to the extent necessary so that the chemical substance . . . no longer presents such unreasonable risk*. Information regarding current workplace practices, included below, will also assist EPA in developing a more narrowly tailored risk mitigation approach with respect to PV29.

Regarding the risk evaluation, briefly stated, CPMA and ACA provided comments stating:

- Manufacturers provided data for *actual exposure times* to evaluate actual risk potential in the workplace. EPA's extrapolation to longer exposure times is not reasonable and not representative of workplace exposure. If EPA expected monitoring data covering longer time periods or with greater airflow, EPA should have communicated testing specifications to the manufacturer in the Section 4 test order or by other means. Air flow typically mimics breathing patterns, and assuming increased air flow would invalidate the results.
- Workers will not be exposed to particles at the nanoscale. Nanoscale particles will agglomerate. It is physically impossible to keep PV29 particles at the nanoscale without considerable effort.
- Lung overload is not toxicologically relevant to workplace exposure or risk, unless the workplace has high volumes of dust in the air so that it overwhelms the respiratory clearance mechanism. Here, the air sampling data does not support the possibility of lung overload.
- Workers typically handle PV29 in a matrix (mixture) as pellets or as a liquid, not in powder form.
- EPA bases its assessment on a carbon black analogue, presenting an additional level of inaccuracy.

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<sup>5</sup> U.S. Environmental Protection Agency, 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 (January 2021) at page 54-56.

In response to EPA's current proposed risk mitigation rule, CPMA is submitting comments detailing the points noted above and other deficiencies in the underlying risk evaluation. ACA supports the comments of CPMA. Like CPMA, ACA recognizes the need to withdraw the current risk mitigation rule and revise the underlying risk evaluation. Confidence in the TSCA process hinges on making this risk evaluation scientifically sound.

### **III. EPA should recognize minimal exposure potential of nanoscale dust particles**

ACA is concerned that EPA developed risk mitigation requirements, in part, based on an assumption of exposure to ultra-fine particulate PV29 dust, as EPA assumes in its risk evaluation. Moreover, as explained in sections below, existing respirator requirements abate any existing risk from dust exposure. In response to EPA's final draft risk evaluation, CPMA provided detailed analysis demonstrating agglomeration of fine PV29 particles, in its December 2020 comment submitted to EPA. ACA incorporates those comments here and requests that EPA review them when determining an appropriate risk mitigation strategy, as required in TSCA Section 6(a). EPA is not prohibited from considering all aspects of the underlying risk evaluation and related comment, to tailor its risk mitigation program appropriately.

Data shows that workers are not exposed to UFP (Ultra Fine Particles) of PV29 as EPA assumed in its risk evaluation. Following publication of the final risk evaluation, CPMA monitored fine particulates at a PV29 manufacturing facility during relevant activities, where "Ultra Fine Particle" or UFP are defined as particles in the 0.02-0.1  $\mu\text{m}$ . The study included measurement of airborne concentration of particles from 0.3 to 25  $\mu\text{m}$ . CPMA has provided EPA with a study report. The study concludes that, UFP (Ultra Fine Particles) includes the primary particle size of 0.043  $\mu\text{m}$ , which is the size EPA assumed and relied upon during its risk evaluation. Most of the particles generated during the PV29 pack-out process were within the 1 to 3  $\mu\text{m}$  size range with the average concentration in this range closer to 3 or approximately 2.5  $\mu\text{m}$ , more than 50 times larger than the size used in EPA's evaluation. In effect, the risk to workers handling "regulated PV29," that is PV29 in particulate form, is overstated. Workers are not at risk of exposure to ultra fine particles (UFP), which includes particles at the nanoscale.

### **IV. EPA's risk evaluation supports classifying PV29 as a non-hazardous nuisance dust**

When analyzing risk from workplace exposure, industrial hygienists typically require identification of a toxicologically relevant threshold. An employer would then implement appropriate engineering controls and/or PPE to mitigate exposure below a toxicologically relevant threshold. Here, EPA identifies lung overload to fine particulate PV29 dust as the toxicologically relevant event. (See p. 66-67, Final Risk Evaluation, Jan. 2021). EPA's risk evaluation does not adequately inform risk mitigation for workplace exposure since it does not provide a concentration of airborne particulates that would lead to lung overload and lung overload is not adequately supported by available data.

Relevant discussion in the risk evaluation assumes that trace amounts would accumulate over time to overload the lung clearance mechanism. EPA assumes that the body's natural clearance

mechanism would not clear any amount of trace particles. This is not a valid assumption for the purpose of identifying an appropriate risk mitigation strategy. It provides no data regarding rates of clearance compared to rates of accumulation. Typically, such data would only be relevant to evaluating chronic exposure to dense air concentrations. Here, EPA is considering exposure to trace levels of dust. For additional information, see comments on the draft final risk evaluation filed by CPMA in December 2020 and resubmitted to the SBAR for review.

EPA is now, during the risk mitigation phase, attempting to develop an ECEL as a toxicologically relevant threshold, although any toxicologically relevant exposure levels should have been determined prior to the risk evaluation. None was determined at that time because PV29 dust causes minimal *actual* workplace risk. EPA provides a theoretical “risk evaluation” for consideration of EPA’s risk mitigation team. Section 6(a) of TSCA does not prevent the risk mitigation team from considering the totality of information and circumstances available to it when determining an appropriate risk mitigation approach. **EPA should carefully consider existing risk mitigation strategies developed by industrial hygienists, who are highly trained to evaluate workplace exposure and have developed methods and references to inform risk abatement.**

Identification of a toxicologically relevant threshold usually starts with identification of hazard characteristics of the substance at issue, as required by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. The chemical PV29 is not classified as hazardous under the OSHA Haz Com or the EU CLP (*EU Classification, Labelling and Packaging Regulation*), the companion regulation in Europe. Both OSHA Haz Com and the EU CLP implement the GHS (*U.N. Globally Harmonized System of Classification and Labelling of Chemicals*).

Since PV29 is not classified as hazardous, under health hazard criteria in the OSHA Haz Com standard and the EU CLP Regulation, it is considered a nuisance dust. EPA’s hazard analysis concludes:

The REACH SDS for C.I. Pigment Violet 29 indicates the presence of an anhydride residual compound which would have concerns for dermal and respiratory sensitization (3,4,9,10-perylenetetracarboxylic dianhydride).<sup>6</sup>

The EPA also conducted a literature review to identify hazard characteristics and did not identify a GHS classification for PV29. OSHA implements internationally accepted criteria for classification of a substance as a “respiratory sensitizer,” referencing animal testing assays and threshold values for the substance in a mixture.<sup>7</sup> PV29 does not meet the criteria for

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<sup>6</sup> U.S. Environmental Protection Agency, 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 (January 2021) at page 65. The EU REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals) is an European Union regulation on chemicals for human health and environmental protection.

<sup>7</sup> See Appendix A.4 of the OSHA Hazard Communication 29 CFR Part 1920.1200.

classification, as noted in the SDS referenced above. As such, PV29 dust in the workplace is considered a “nuisance dust” and not a hazardous dust.

OSHA sets minimum requirements for assessing nuisance dust hazards. In the workplace, industrial hygienists consider OSHA requirements with the totality of information available. This includes a variety exposure levels, such as threshold limit values (TLVs) published by the American Conference of Governmental Industrial Hygienists (ACGIH), the National Institute for Occupational Safety and Health (NIOSH) recommended exposure levels, OSHA permissive exposure limit (PEL), as well as manufacturer determined levels, and levels implemented in other jurisdictions, etc. Considering these sources, a company would determine the most protective airborne threshold concentration. Companies then implement exposure controls for any possible exposure at the “industry action level,” usually at half of the reference airborne threshold concentration. This is standard practice for all chemicals, not just PV29.

Companies are required to perform such an analysis under the General Duty Clause at Section 5 of the *Occupational Safety and Health Act of 1970*. As such, an OSHA PEL would only be the starting point of a company’s evaluation of the level of protection necessary. Both OSHA and California OSHA prescribe a PEL for nuisance dust at 5 mg / m<sup>3</sup>, with monitoring methods, as noted in OSHA’s Occupational Chemicals Database.<sup>8</sup> Since EPA has not identified a toxicologically relevant exposure threshold, ACA recommends that the EPA defer to the value identified by both OSHA and California OSHA of 5 mg/m<sup>3</sup> should be the reference value for risk mitigation activities.

#### **V. OSHA’s respirator protection standard provides comprehensive safety requirements**

Having determined a reference exposure threshold, OSHA’s respiratory protection standard at 29 CFR 1910.134 provides existing requirements for risk mitigation. NIOSH also provides guidance for the selection of respirators and related regulations.<sup>9</sup> Additionally, OSHA’s comprehensive standard includes requirements for determining when a respirator is necessary, a written respiratory protection program, respirator selection, fit testing, medical evaluations, worker training, record-keeping, etc.<sup>10</sup> The standard requires compliance when engineering controls do not abate dust exposure to an acceptable reference value. ACA recommends that EPA adopt and reference existing OSHA requirements of this section to address any requirements related to respirator use, including record keeping requirements. Imposing duplicative EPA-mandated respirator and record keeping requirements imposes additional and unnecessary compliance costs on all businesses. The impact on small businesses can be particularly pronounced.

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<sup>8</sup> See OSHA, “Particulates Not Otherwise Regulated, Total and Respirable Dust (PNOR)” (last updated on Jun. 6, 2023), <https://www.osha.gov/chemicaldata/801>.

<sup>9</sup> National Institute for Occupational Safety and Health (NIOSH), The NIOSH Pocket Guide to Chemical Hazards, March 7, 2016, <https://www.cdc.gov/niosh/npg/pgintrod.html#mustread>.

<sup>10</sup> OSHA regulations are under Title 29 CFR Part 1910 to 1926.

## **VI. ACA supports EPA's conclusion that PV29 particulates are not bioavailable and therefore downstream products should not be regulated**

ACA supports EPA limiting risk mitigation requirements based on a lack of bioavailability of PV29 particles in downstream products. Both the IARC (International Agency for Research on Cancer) and California's OEHHA (Office of Environmental Health Hazard Assessment) considered the hazards of particles in a paint matrix when considering potential carcinogenicity of certain paint components. A key consideration for classifying chemicals as potential carcinogens is the "availability for exposure" presented by particulates when "bound" in a wetted-paint or coatings mixture. Given the published findings of IARC and California's OEHHA, the "availability for exposure" factor has resulted in clear moderating statements on carcinogen classifications.

The IARC's monographs, for example, include the following mitigating statement for carbon black and titanium dioxide as present in paints and coatings:

### FOR CARBON BLACK

"Operators in user industries who handle fluffy or pelleted carbon black during rubber, ***paint and ink production are expected to have significantly lower exposures to carbon black than workers in carbon black production.*** Other workers in user industries who handle it occasionally have little opportunity for exposure."

And further...

***"End-users of these products (rubber, ink or paint) are unlikely to be exposed to airborne carbon black particles, which are bound within the product matrix."***

"Many workers were exposed to carbon black in bound matrices such as paint or rubber. It is probable that workers exposed to carbon black in this study were exposed to lower levels than those in other studies."

### FOR TITANIUM DIOXIDE

***"No significant exposure to primary particles of titanium dioxide is thought to occur during the use of products in which titanium dioxide is bound to other materials, such as in paints."<sup>11</sup>***

California's OEHHA issued similar language for classification under California's *Safe Drinking Water and Toxic Enforcement Act (Prop. 65)*, when issuing a Safe Use Determination for crystalline silica:

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<sup>11</sup> International Agency for Research on Cancer (IARC), *IARC Monographs on Evaluation of Carcinogenic Risks to Humans Volume 98 Carbon Black, Titanium Dioxide, and Talc*, IARC, 2010. Can be found at <http://monographs.iarc.fr/ENG/Monographs/vol93/index.php>.

*“Most of the crystalline silica particles in the paints were above respirable size (10 µm) and partitioned out of the respirable paint aerosol when the aerosol was generated. This is the likely reason for the lack of crystalline silica detection in respirable wet paint aerosol under these testing conditions. Since NPCA (now ACA) took a reasonable approach in its effort to measure crystalline silica from the spraying activity, i.e., the pooling of filters, **OEHHA believes the wet aerosol portion of the exposure may be much less toxicologically significant than that produced from the dusts that result from sanding.***

*A number of factors may tend to increase or decrease estimates of exposure relative to the approach used to develop the exposure levels described above. **We believe, on the whole, that the assumptions made are likely to have resulted in overestimates of exposure levels from the average use of interior flat latex paint.**”<sup>12</sup>*

Considering these authoritative findings strongly indicate the lack of exposure and risk associated with particles integrated in a wetted mixture, it is not appropriate to assume paint and other downstream products are a source of exposure. Such products are not associated with an adverse health effect from a hazard associated with a chemical component when bound in a matrix. ACA encourages EPA to consider these other authoritative findings as the agency determines the risk and develops mitigating strategies in order to provide a more tailored and appropriate methodology to reducing risk.

## **VII. Risk Mitigation Strategies**

ACA strongly suggests revising the underlying risk evaluation prior to proceeding to risk mitigation. ACA is providing the following suggestions related to risk mitigation as a secondary, less desirable, approach due to the failure to incorporate the *weight of the evidence* and the *best available science* into the risk evaluation to justify proposed risk mitigation strategies.

### **A. Risk mitigation requirements affecting conditions of use related to paint and coating Manufacturing.**

Several aspects of EPA’s proposed risk mitigation strategy are not clearly justified by the underlying risk evaluation. In effect, EPA goes beyond the requirements of TSCA §6(a), limiting risk mitigation strategies to the extent necessary to mitigate a clearly defined risk. EPA prescribes requirements related to handling of “regulated PV29,” disposal, cleaning and regulated areas that are not adequately supported in the risk evaluation. These are detailed below with suggestions about how to narrowly tailor requirements based on the risk evaluation.

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<sup>12</sup> OEHHA Safe Use Determination for Crystalline Silica  
[http://www.oehha.org/prop65/CRNR\\_notices/safe\\_use/sylicasud2.html](http://www.oehha.org/prop65/CRNR_notices/safe_use/sylicasud2.html)

- 1) *EPA must clarify the definition of “regulated PV29” so it more accurately reflects PV29 subject to EPA’s risk evaluation.*

**EPA’s risk mitigation requirements should only apply where the dry powder contains at least 80% of regulated PV29.** EPA’s risk evaluation for the CoU for *Processing: Incorporation Into Formulation, Mixture, or Reaction Products in Paints Coatings* is based on an assumption that:

*[p]rocessors of PV-29 for paint and coating manufacturing receive the chemical at 80% concentration in powder bags that are manually opened and dumped into a mixer where it is missed and formulated into a tint paste.*

EPA has no basis to require workplace controls to reduce the alleged risk from PV29 (which is disputed to begin with) where processors of PV29 for paint and coating manufacturing are using dry powders containing **less than** 80% of PV29.

Paint and coating manufacturers may use dry powders containing as little as 1% to 5% of PV29. Both EPA’s proposed regulatory action and its alternative regulation action are not justified for paint and coating manufacturers using dry powders containing such small amounts of PV29. EPA’s premise for determining unreasonable risk assumes that the dry powders used contained at least 80% of PV29. Risk mitigation must be limited accordingly.

- 2) *EPA should clarify that disposal requirements only apply when handling regulated PV29.*

The disposal requirements as written are vague and appear to apply to any mixture, including liquid mixtures, containing PV29. EPA must clearly limit these requirements to situations where there is the potential for inhalation exposure to respirable *regulated PV29*. The unreasonable risk determination for this CoU is based on disposal facilities only. In effect, this requirement must be scoped so it is limited appropriately.

- 3) *EPA must also scope the cleaning requirements in an appropriate manner.*

The proposed area cleaning requirements under both the proposed regulatory action and the alternative regulatory action are excessive, impractical, and not reasonably tied to any risk determination from the respirable fraction of PV29. EPA unreasonably assumes that “residue” left behind after processing of regulated PV29 into a paint presents any inhalation risk.

Based on this assumption, EPA proposes the following:

- “EPA is proposing that each owner or operator create and implement a cleaning plan for equipment and area cleaning where regulated PV29 has been manufactured, processed, used, or disposed of.”
- “As part of the equipment and area cleaning requirements, EPA is proposing to require equipment and the area in which the equipment is housed to be cleaned within 24 hours following manufacturing, processing, use or disposal of regulated PV29.”

- “Surfaces of the equipment that have contact with regulated PV29 as part of operation or the area where the equipment is located would need to be free of residue, meaning that no residue is left on surfaces in the area, such as the outer housing of equipment and places where dust-like particles typically settle, such as the floor; for example, a wet, white cloth, swab, or other similar cleaning fabric will not have visible color after contact with the surface.”
- Recordkeeping: “plan and previous versions; (2) The dates, duration, and completion status of equipment and area cleaning each time a cleaning plan is executed”

These requirements are overly burdensome, considering that EPA has not established an inhalation risk from PV29 residue, especially when incorporated into a paint mixture or otherwise within a matrix.

*4) Requirements that apply to a regulated area are overly broad and not justified by the risk evaluation.*

EPA proposes defining a *PV29 regulated area* broadly as *"An area where a regulated PV29 container is open or in use, an area where equipment containing regulated PV29 is in use or has not yet been cleaned, or an area where cleaning activities are occurring."* This definition is overly broad since there may be no actual or potential dust generation associated with these activities. For example, in paint manufacturing, residue often remains in the enclosed systems after the initial powder addition. **The PV29 Regulated Area requirements should only apply to areas where there is actual or reasonably probable airborne dust generation from use of powders containing unbound, respirable PV29, such as active addition of a dry powder in the paint and coating manufacturing process.**

Likewise, restricted access and respiratory protection, if required, should only be necessary with respect to a PV29 regulated area from the point of time when there is actual dust generation from use of powders containing unbound, respirable PV29 to the point in time when all dust is settled and no longer airborne.

With respect to the proposed cleaning requirements, EPA has not provided any justification that visible “residue” left behind after processing of regulated PV29 in the paint and manufacturing process presents any inhalation risk. Further, EPA appears to propose an impossible “free of residue” cleaning standard. The agency appears to define this standard as no visible color present on a cleaning fabric to justify the area as clean. Further, such a standard is unnecessary to prevent alleged risk in the paint and manufacturing COU, since PV29 would not be used across all batches in paint manufacturing. As EPA is aware, paint manufacturing has no dedicated equipment for manufacturing coatings containing Regulated PV29. Regulated PV29 is only used occasionally as a pigment as dictated by customer demand. As such the cleaning requirements are not practical for occasional batches and closed systems.

In addition, the 24-hour period to conduct cleaning after manufacture is not feasible or justified. EPA should not impose a prescriptive time limit. Such limits would require a regulated entity to bring in shift workers just to meet such cleaning requirements. The risk evaluation does not establish an imminent risk requiring a time limit. **Since this is not an imminent risk, regulated entities within the paint and coating manufacturing COU should be provided with flexibility to follow their standard maintenance procedures and not be held to a prescriptive cleaning standard or time limit in which to conduct cleaning.**

At most, the PV29 regulated area requirements should apply during housekeeping and cleaning activities at the end of a shift, in the PV29 Regulated Area where *Regulated PV29* was used during that shift. Further the requirements should only be triggered where housekeeping and cleaning activities have potential to generate airborne dust.

**B. EPA should not finalize workplace requirements on downstream industrial and commercial use of paints and coatings.**

Several COUs prescribe workplace controls applying to downstream use of products containing “regulated PV29.” EPA clearly intends to limit requirements to powder-formed PV29, but applicability to downstream products remains vague, considering that paint and coatings are often in liquid form and PV29 would be in a matrix. EPA must clarify these requirements.

Due to the lack of bioavailability of “regulated PV29,” ACA recommends that EPA not impose any workplace requirements, such as respiratory protection and area cleaning, on the COUs for:

- Industrial use and commercial use in automobile paints and coatings, original equipment manufacturing and refinishing, and
- Industrial and commercial use in coatings and basecoats for paints and coatings.

EPA has already found that when PV29 is incorporated into a matrix of paint and other liquid media, PV29 does not retain the original dry particle properties of its original form. Studies have found that pigments embedded in the paint matrix are not released during application or sanding. Thus, based on published literature, exposure to PV29 would not occur during application or sanding of paint as it would not be released from the paint matrix and is no longer bioavailable. This applies to sanding and grinding, since they involve use of the dried paint containing PV29. It also applies to spray painting, since PV29 is bound in a wetted matrix. Accordingly, EPA has no basis to impose any workplace requirements for PV29 on the industrial and commercial use in paints and coatings CoUs.

**C. Proposed workplace requirements under both the proposed regulatory action and the alternative regulation action are unnecessarily prescriptive and unjustified with respect to the paint manufacturing COU.**

ACA recommends EPA provide for flexibility in “workplace requirements” regarding the controlled exposure to *Regulated PV29*, and that PV29 should be defined as PV29 that is at least 80% of the dry powder. Regulated entities should be the given option to either:

**Option 1:** Allow for the use of engineering controls to reduce dust while using APF 10 respirators where activities could generate airborne dust. This approach is similar to EPA’s proposed alternative regulatory action, but without the proposed required *Regulated Area or Cleaning Requirements*, due to reasons stated above; or

**Option 2:** Allow industry to follow the hierarchy of controls. This approach has precedent in the proposed risk management rule for 1-BromoPropane.<sup>13</sup> The requirement to implement the hierarchy of controls could be triggered by a qualitative exposure assessment or using the OSHA respirable particulates not otherwise regulated (PNOR) PEL of 5 ug/m<sup>3</sup> as a surrogate exposure limit for PV29. These triggers are currently required due to a lack of reliable test methods. They could remain in place until a chemical-specific inhalation exposure monitoring method can be developed for PV29 that has a limit of detection measurable against an appropriately calculated existing chemical exposure limit (ECEL), from a revised risk evaluation.

*(a) Proposal requiring APF 50 Respirators*

We strongly object to EPA’s proposed regulated action requiring the use of APF 50 respirators in a “Regulated PV29” area. As proposed by EPA, this would require the use of APF 50 respirators up to 24 hours or longer to the extent EPA’s impossible cleaning standard could be met.

EPA has provided no justification for requiring the use of APF 50 respirators to prevent alleged unreasonable risk, especially with respect to the paint and coating manufacturing COU where engineering controls minimize dust levels.

Under the current proposal, workers in a regulated area would wear APF 50 respirators throughout the shift during normal, routine operating conditions, although any potential inhalation exposure is limited to 30 minutes. **This excessive and unnecessary use of AP-50 respirators would hinder vision, communication, hearing, and movement thereby increasing risks to the wearer’s safety or health.** Any respirator use reduces worker visibility, which is critical in a production area with large moving equipment, puts stress and strain on the body

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<sup>13</sup> 1-Bromopropane (1-BP); Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 65085 (Aug. 8, 2024).

systems (heart and lung), and reduces worker satisfaction. Excessive use of respirators hinders quality of work, worker safety and satisfaction.

EPA has agreed, as part of the final trichloroethylene (TCE) Risk Management Rule, that it is not feasible to rely on full-time use of respirators to eliminate or reduce EPA-identified unreasonable risk to workers.<sup>14</sup>

**Respirator use should be limited to the duration of short-term, high-risk exposure tasks to airborne Regulated PV29 or cleanup of spills of Regulated PV29.** For example, respirator use should only be required where there is dust generation such as active addition and/or mixing of a powder containing Regulated PV29 as part of paint and coating manufacturing. We take objection to EPA's suggestion that respirator requirement would apply for any activity involving regulated PV29, including when a container is merely opened or when "equipment containing PV29 is in use or has not been cleaned" as there may be no dust generation associated with these activities (e.g., enclosed systems after initial powder addition).

These concerns also apply to EPA's proposed regulated action as drafted. In effect, ACA would request EPA to consider adopting ACA's suggested *Option 1*, incorporating engineering controls, as detailed above.

*(b) EPA's proposed monitoring requirements.*

ACA remains concerned regarding the frequency and lack of utility of EPA's proposed monitoring requirements. EPA's proposed monitoring frequency is impractical, unreasonable, and unnecessary due to the reasons stated previously. That is, industry does not have a method to identify PV29 in isolation from other particulate dust. In effect, all forms of respirable particulate are included in monitoring results. Typically, requirements would be triggered by potential overexposures, but in this case, EPA has not established an exposure limit, so any monitoring result triggers requirements rendering monitoring data irrelevant.

Additionally, EPA appears to be arbitrarily requiring the NIOSH 0600 LOD as a default exposure limit for all forms of respirable particulate **as there is no monitoring method to specifically identify PV29 as noted above.** The results using OSHA's general monitoring method for respirable dust will include more substances than just PV29 in the results as it is measuring all respirable particulate within the breathing zone.

The monitoring requirement is unnecessary in both the current proposal and in EPA's proposed alternative regulatory action because EPA is requiring prescriptive workplace requirements, namely engineering controls and respirator use.

To the extent monitoring is required, EPA should adopt the OSHA respirable PNOR PEL of 5 ug/m<sup>3</sup> as a surrogate exposure limit for PV29, until a chemical-specific inhalation exposure

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<sup>14</sup> Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 74712, 74735-37, 74762 (Oct. 31, 2023).

monitoring method can be developed for PV29 that has a limit of detection that can be measured against an *appropriately calculated ECEL* for PV29 that is based on a revised risk evaluation.

The failure to establish adequate monitoring methods with accurate exposure thresholds affects the efficacy of all aspect of EPA's proposed risk mitigation requirements. Because of this, ACA also objects to the proposed PV29 Regulated Area and Cleaning requirements under the EPA's proposed Alternative Regulatory Action.

*(c) Importance of incorporating the hierarchy of controls*

ACA's proposed Option 2 (noted above) follows the accepted *hierarchy of controls* approach to protect workers based upon exposure-based decision-making criteria. Please consider the following:

- EPA's current proposal for the Proposed Regulatory Action and Alternative Regulatory Action fails to accommodate **an exposure-based decision-making criteria for selection of feasible controls**, considering other factors in the work environment. A fundamental concept in identifying the appropriate level of risk mitigation rests on an understanding that using a prescriptive approach potentially leads to more severe acute hazards related to unintended consequences of wearing excessive PPE, such as heat stress, caught in machinery, slip, trips, and falls, spills, cross contamination to other work areas, etc.
- Concerns about maintaining an appropriate level of a prescribed risk mitigation strategy are echoed in TSCA Section 6(a), requiring that EPA prescribe strategies "to the extent necessary" to mitigate risk. Implementation of TSCA Section 6(a) requires accuracy in the underlying risk evaluation. **Due to the speculative nature of the risk evaluation, ACA recommends revising the entire risk evaluation to more clearly reflect potential handling times, industry practice and appropriate hazard identification.**
- In the alternative, **EPA should revise the proposed rule to explicitly recognize and allow regulated entities an option for traditional IH hazard identification, risk assessments, and control management evaluation tools to evaluate worker exposure and effectiveness of controls. These techniques are advised by NIOSH, OSHA, AIHA, and sound industrial hygiene practice.**
- Specifically, this option should be non-prescriptive and enable regulated entities to determine how to most effectively minimize inhalation risk of respirable regulated PV29 based on what works best for their workplace consistent with OSHA's current hierarchy of controls approach.
- The hierarchy of controls is a method of identifying and ranking controls to protect workers from hazards and reduce exposure risk. The pyramid is upside down, and

controls are arranged from the most to least effective. From the top, controls are elimination, substitution, engineering controls, administrative controls and personal protective equipment. Layers of protection or a combination of control methods are used to best protect workers. For example, a local exhaust system (an engineering control) requires training, periodic inspections, and preventive maintenance (administrative controls). Sometimes, respirators are still necessary even when using a ventilation system. Feasibility of controls is also necessary to consider. It is imperative to involve the workers and their supervisors who know the operation the best in the evaluation of feasibility and effectiveness of controls.

- EPA should amend its proposed workplace requirements to allow this option to accommodate a **risk-based management approach to be used to demonstrate effective worker protection from respirable PV29 (if any is present), and use reasonable layers of protection, based on the hierarchy of controls pyramid. EPA mistakes the hierarchy of controls for a regimented, prescriptive set of controls that must be applied sequentially; that is simply not how the hierarchy of controls functions in practice.**
- Under this option, **respiratory protection should not be mandatory unless a qualitative exposure assessment indicates a need or a quantitative IH exposure monitoring program indicates the need based on exposures above the OSHA respirable PNOR PEL of 5 ug/m<sup>3</sup>.** The OSHA respirable PNOR PEL would act as a surrogate exposure limit for PV29 unless and until a chemical-specific inhalation exposure monitoring method can be developed for PV29 that has a limit of detection that can be measured against an appropriately calculated ECEL for PV29 that is based on a revised risk evaluation.
- PPE selection criteria should follow OSHA 29 CFR 1910.132 requirements for a hazard and PPE selection assessment.

### **VIII. Responses to Specific EPA Requests for Comment**

ACA strongly recommends revision of the PV29 risk evaluation. As a less desirable alternative to revising the risk evaluation, ACA recommends adopting its Option 1 or Option 2 noted above. EPA has suggested issues for specific comment addressing its proposed risk mitigation strategy and its proposed *regulatory alternative*. Noting that neither of EPA's proposals are based on an accurate understanding of risk, ACA submits the following responses, based on explanations provided above.

As a general matter, EPA should note that its proposed risk mitigation requirements do not take into account the principles of exposure probability risk, requiring consideration of:

- exposure duration

- distance from the source (method to establish regulated area boundary distance),
- amount of PV29 in the material (which could be 1% or lower) and
- particle size and potential to get to the deep air sacs of the lungs, potential dustiness (with the exception of dry), or frequency of use.

Therefore, there is no measure as to exposure control effectiveness or use of the hierarchy of controls pyramid. If qualitative exposure assessments were conducted, exposure could be re-evaluated prior to controls, with current controls, and post-controls to determine adequacy of controls as they relate to the principles of exposure risk probability.

Using an industrial hygiene qualitative exposure assessment strategy to determine exposure potential [dose = hazard severity X exposure duration and frequency] will assist with determining effectiveness and need for a phased exposure control strategy. The first step to this process is understanding the hazard severity of PV29. This is a pre-determined level, not determined by regulated entities.

On-site factors affecting exposure remain in control of regulated entities, such as the exposure duration (minutes in a day) and frequency (days in a year) to known tasks that have high exposure potential. Regulated entities would then reduce factors related to exposure potential by process control solutions, reducing the exposure time per task, etc. Reducing the duration and frequency of high-risk tasks per worker, as well as reducing the general production floor work area levels, would greatly reduce potential for worker exposure. A tool such as the American Industrial Hygiene Association (AIHA) qualitative industrial hygiene exposure tool could be used by workplaces to drive down exposures.<sup>15</sup>

Noting the importance of on-site exposure considerations, ACA submits the following responses to issues for comment that EPA identifies:

#### *1. Written cleaning plan*

EPA requests comment regarding whether EPA should have more prescriptive requirements for the cleaning plan. As described above, ACA objects to the proposed cleaning requirements as burdensome, impractical, and not reasonably tied to any risk determination from the respirable fraction of PV29. To the extent EPA proceeds, the cleaning plan should be written locally by the facility owner/operator, since it will need to be based on the conditions and use on site.

The cleaning plan is linked to residue and on-site dust. EPA would need to better define an acceptable cleaning level for de-regulation of a PV29 Regulated Area. Since there is no acceptable ECEL, the exposure criteria set seems to indicate “residue free” as the acceptable cleaning level. This is impractical and unrealistic for facilities since PV29 is one of many

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<sup>15</sup> The American Industrial Hygiene Association (AIHA) website provides tools available to the public and in multiple languages, <https://www.aiha.org/public-resources/healthierworkplaces/healthier-community-resources/apps-and-tools-resource-center/aiha-risk-assessment-tools>.

particulates in a facility. PV29 dust is not measured in isolation. The requirement to clean every 24-hours is not justifiable and is further complicated by 24-hour operations and shared equipment with other materials. The clearance level communicated is essentially “free of residue” which is impractical and excessive.

## *2. Warning Signs:*

EPA is soliciting comment on requiring warning signs to demarcate PV29 regulated areas. If regulated areas are determined to be required, warning signs should be used to demarcate the area. It remains unclear as to the hazard and effect level that should be conveyed on any warning signs. Although OSHA's General Industry Standard for Beryllium provides requirements in that particular instance, the requirements in OSHA's General Industry Standard for Crystalline Silica are a more appropriate reference source for PV29, especially given the paint and coatings industry's familiarity with it.<sup>16</sup>

## *3. Respirator service life*

EPA requested comment regarding minimum service life of non-powered air-purifying respirators such as those required in OSHA's General Industry Standard for Benzene.<sup>17</sup> For reasons noted above, ACA strongly objects to mandated use of APF 50 respirators. ACA notes that the appropriate filter for non-powered air purifying respirators is a P100 HEPA filter. The service life of this filter is when breathing becomes difficult. The filtration effectiveness will increase with more material, but dust loading of the filters will put more body burden and stress on the system. Typically, facilities establish timeframe to replace their respirator filters, based on exposure on-site exposure considerations. For example, depending on use a site might prescribe replacement at least every 6 months or when breathing becomes difficult.

Since no exposure limit for Regulated PV29 has been established, the use of a particular level of respiratory protection and requirement of fit testing is impractical and excessive. For instance, the act of fit testing a respirator is to verify that the assigned protection factor is adequate to maintain exposure below the occupational exposure limit. Even for radiological exposures incorporate the principle of exposure time. This is informative because radiological exposures do not always have an established exposure limit, but protection is as low as reasonably achievable (ALARA). ALARA is achieved using the principals of exposure time, distance from the source, and shielding. Appropriate levels of control could be applied without an established occupational exposure limit, based on a qualitative risk priority score, based on site-specific considerations.

## *4. Training*

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<sup>16</sup> OSHA's General Industry Standard for Beryllium can be found at 29 CFR 1910.1024(m)(2); OSHA's General Industry Standard for respirable silica can be found at 29 CFR 1910.1053

<sup>17</sup> OSHA's General Industry Standard for Beryllium can be found at 29 CFR 1910.1028(g)(3)(D).

EPA is requesting comments regarding whether facilities should provide additional workplace training in areas where regulated PV29 is present. In general, chemical specific training is recommended when workers must be informed of a clearly identified hazard to justify regulated area entry authorization and cleaning protocols. However, in the case of PV29, EPA has not adequately or clearly stated the hazards associated with Regulated PV29 to justify any need for additional workplace training. Further, hazard classification is not according to the OSHA Hazard Communication standard, causing discrepancies in fundamental understanding of potential hazard and associated risk.

#### 5. *Recordkeeping*

EPA requests comment regarding timeframes for recordkeeping and downstream notification requirements. Harmonizing recordkeeping associated with respiratory protection with requirements in OSHA 29 CFR 1910.134 would normally be a reasonable approach. However, recordkeeping of the dates, duration, and completion status of equipment and area cleaning *each time a cleaning plan is executed is overly burdensome and unreasonable.*

#### 6. *Primary alternative regulatory action*

EPA requests comment about its primary alternative regulatory action and whether any elements of the primary alternative regulatory action should be considered as EPA develops the final regulatory action.

##### (a) Engineering controls and respiratory protection.

From the alternative, ACA recommends requiring engineering controls and respiratory protection with APF of 10 for the following *conditions of use*:

1. Manufacturing
2. Processing
3. Incorporation into formulation, mixture or reaction products in paints and coatings
4. Incorporation into formulation, mixture or reaction products in plastic and rubber products
5. Processing intermediate in the creation or adjustment of color of other perylene pigments

Requiring respiratory protection with APF of 50 for the following conditions:

1. Processing
2. Recycling
3. Industrial and commercial use: paints and coatings—automobile (original equipment manufacturing and refinishing)
4. Industrial and commercial use: paints and coatings—coatings and basecoats
5. Industrial and commercial use: merchant ink for commercial printing
6. Disposal

OSHA chemical substance specific standards, such as 29 CFR 1910.1024 Beryllium, referenced by EPA in the Proposed Rule, state the following:

*The employer must use engineering and work practice controls to reduce and maintain employee airborne exposure to beryllium to or below the PEL and STEL, **unless the employer can demonstrate that such controls are not feasible.** Wherever the employer demonstrates that it is not feasible to reduce airborne exposure to or below the PELs with engineering and work practice controls, the employer must implement and maintain engineering and work practice controls to reduce airborne exposure to the lowest levels feasible and **supplement these controls using respiratory protection** in accordance with paragraph (g) of this standard.*

Without the statements in bold, employers do not have an incentive to invest in high-cost engineering control, instead relying on over-use of respiratory protection with administrative controls required in this rule. As described above, over-use of respirators reduces visibility of workers, which is critical in a production area with large moving equipment, puts stress and strain on the body systems (heart and lung), and reduces worker satisfaction at a minimum. Respirators should not be required throughout the day, during normal operations.

*(b) Monitoring for PV29 dust*

EPA seeks comments regarding monitoring requirements under the primary alternative regulatory action:

*EPA would use NIOSH method 0600 in place of a chemical-specific monitoring method because no analytical monitoring method currently exists for PV29. The respirable dust method would be used in place of a chemical specific monitoring method to have a way of measuring airborne regulated PV29 workplace exposure. Monitoring would be required to occur at least once every 3 months during when regulated PV29 is manufactured or is in use. If the concentration of airborne dust is above the NIOSH 0600 LOD, monitoring would need to occur at least once every 3 months. If the concentration of airborne dust is below the LOD, monitoring would need to occur at least once every 6 months.*

Due to the lack of adequate monitoring methods for PV29, this monitoring frequency is impractical, unreasonable, and unnecessary. All forms of particulate would be included in any measurements. Measurements would be irrelevant.

For reference, one paint manufacturer notes monitoring of respirable particulate matter collected over the previous 15 years in each plant that has handled PV29. Results show particulate matter less than 0.3043 mg/m<sup>3</sup> or less with 95% confidence.

*(c) Monitoring for Inhalation Exposures*

In addition to PV29 dust levels, EPA requests comment about monitoring for inhalation exposures, including the amount of time needed to develop an inhalation exposure monitoring method or how to adapt existing monitoring methods (See Unit V.5).

Absent a revision of the underlying risk evaluation, ACA recommends that the primary regulatory proposal be delayed until a monitoring method and exposure limit is established. Alternatively, EPA could adopt:

- (1) qualitative exposure assessments to confirm adequacy of controls and acceptable exposure of workers; or
- (2) a reference to the OSHA respirable PNOR PEL of 5 ug/m<sup>3</sup> as a surrogate exposure limit for PV29 unless, until a reliable, chemical-specific inhalation exposure monitoring method can be developed for PV29 that has a limit of detection that can be measured against an appropriately calculated ECEL for PV29 that is **based on a revised risk evaluation**.

*(d) State-of-the-art risk mitigation techniques*

EPA requests comments regarding relevant state-of-the-art equipment, engineering and administrative controls, and monitoring for inhalation exposures. Dust collection engineering controls are well established and used in many particulate exposure control industries to control beryllium, crystalline silica, hexavalent chromium, arsenic, lead, cadmium, etc.

*(e) Current PPE practices*

*EPA requests comments on current PPE practices within affected facilities using regulated PV29 in any of the conditions of use. (Unit VI.)* Standard practices in industrial hygiene related to respiratory protection allow use of an interim control measure, until more advanced engineering and work practice controls can be used to reduce chemical exposure potential below the occupational exposure limits. Employers may continue to allow voluntary use of interim control measures to abate risk perceived to be in excess of established exposure limits.

*(f) EPA's analysis of bioavailability of PV29 particles*

EPA is requesting public comment on the interpretations of risk related to non-particulate forms of PV29, including PV29 bound in a matrix like paint or other liquids. EPA also requests comment regarding uses that might be associated with exposure, such as aerosol spraying, sanding or grinding dry paint that could render PV29 biologically available or possibly pose an inhalation exposure risk.

As detailed above, ACA strongly agrees with EPA's interpretation that when PV29 is incorporated into a matrix of paint and other liquid media, it does not retain the original dry particle properties of its original form. Studies have also found that pigments embedded in a paint matrix are not released during application or sanding. That is, dust from sanding remains in matrix form and does not degrade into its component ingredients. Based on published

literature, it is unlikely that significant exposure to PV29 would occur during application or sanding of paint as it would not be released from the paint matrix and is no longer bioavailable. This applies to spray painting, sanding, and grinding, since they involve use of the dried paint containing PV29. Please consider the references noted above from IARC (International Agency for Research on Cancer) and California's OEHHA (Office of Environmental Health Hazard Assessment) recognizing the lack of bioavailability for chemicals bound in a paint matrix.

Considering the lack of risk, EPA should revise notification requirements for downstream handling of end-use products. For example, notification should not be required to waste vendors, since waste does not pose inhalation or environmental concerns, as recognized by EPA. In any case, used product would be bagged and not handled directly by waste vendors.

## **IX. Conclusion**

OSHA's Hazard Communication standard identifies PV29 as a non-hazardous, nuisance dust. EPA recognizes this in its final risk evaluation, but nonetheless chose to identify PV29 as a hazard, which is not supported by the *weight of the evidence*. Similarly, EPA's risk evaluation is a product of unwarranted assumptions (exposure times, exposure levels, exposure to nano-scale dust particles, etc.), resulting in a high-degree of inaccuracy. The underlying risk evaluation did not provide the risk mitigation team with enough information to develop risk mitigation requirements that are clearly justified. The proposed risk mitigation rule does not meet the requirement of TSCA Section 6(a), requiring that risk mitigation is only "to the extent necessary," but not in excess of requirements needed to abate risk. ACA strongly recommends that EPA revise the underlying risk evaluation with better contextualization of information, hazard identification and recognition of existing practices affecting exposure.

As a secondary, less desirable approach, ACA provides the following suggestions in response to issues raised in EPA's proposed risk mitigation rule:

- EPA should revise the underlying risk evaluation to better contextualize industry-submitted data, remove unwarranted assumptions and consider current risk abatement practices affecting actual exposure.
- EPA should carefully consider existing risk mitigation strategies developed by industrial hygienists, who are highly trained to evaluate workplace exposure and have developed methods and references to inform risk abatement.
- EPA should limit any risk mitigation requirement considering lack of bioavailability of PV29 in downstream products.
- EPA's risk mitigation requirements should only apply where the dry powder contains at least 80% of regulated PV29. EPA should amend the definition of "regulated PV29" accordingly.

- EPA should not propose disposal requirements affecting end-of-life disposal of PV29-containing products, since PV29 is bound in a matrix.
- EPA should not finalize equipment cleaning requirements and related record-keeping requirements, since EPA has not established risk from residue, especially from products with PV29 incorporated into a matrix. EPA's "free of residue" cleaning standard is not implementable and not necessary for formulation of paints with PV29.
- PV29 regulated area requirements are overly broad, including areas with little to no risk of inhalation of PV29 containing dust.
- EPA should not finalize the cleaning requirement as proposed. Requiring cleaning within a 24-hour period is arbitrary, excessive and unduly burdensome. Paint and coatings manufacturers should be allowed to follow standard cleaning practices since this is exposure from residue is not an imminent risk.
- Due to the lack of bioavailability of "regulated PV-29," ACA recommends that EPA not impose any workplace requirements, such as respiratory protection and area cleaning, on the COUs for:
  - Industrial use and commercial use in automobile paints and coatings (original equipment manufacturing and refinishing, and
  - Industrial and commercial use in coatings and basecoats for paints and coatings.
- Amend the risk mitigation proposal to allow compliance with one of two options:
  - Option 1 – Incorporate engineering controls, while requiring limited use of APF-10 respirators for dust-causing activities.
  - Option 2 - Allow industry to follow the hierarchy of controls.
- Don't finalize the requirement for APF-50 respirators as being excessive and potentially causing additional hazards.
- Monitoring requirements are not feasible and should not be finalized since a monitoring method does not exist. To the extent monitoring is required, EPA should adopt the OSHA respirable PNOR PEL of 5 ug/m<sup>3</sup> as a surrogate exposure limit for PV29, until a chemical-specific inhalation exposure monitoring method can be developed for PV29 that has a limit of detection that can be measured against an *appropriately calculated ECEL* for PV29 that is based on a revised risk evaluation.
- EPA should revise the Proposed Rule to explicitly recognize and allow regulated entities an option for traditional IH hazard identification, risk assessments, and control management evaluation tools to evaluate worker exposure and effectiveness of

controls. These techniques are advised by NIOSH, OSHA, AIHA, and sound industrial hygiene practice.

ACA appreciates the opportunity to submit these comments. Please feel free to contact us if you have any questions.

Sincerely,

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