

April 21, 2022

Todd Coleman
Office of Pollution Prevention and Toxics (7404T)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Re: Docket No. EPA-HQ-OPPT-2016-0725
Submitted electronically via: www.regulations.gov

Dear Mr. Coleman:

The American Coatings Association ("ACA")¹ 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 the SBAR to help ensure effective risk mitigation strategies under the *Toxic Substances Control Act* (TSCA). ACA is providing this submission as a Small Entity Representative (SER) for EPA's consideration during sessions of the Small Business Advocacy Review Panel (SBAR Panel).

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 paints, coatings, sealants and adhesives whose manufacturing processes or products may be affected by the outcome of EPA's risk evaluations for several of the high priority chemicals, including small business using raw materials with PV29. ACA and its members have submitted comment and met with EPA at various stages of the EPA risk evaluation, and we appreciate the opportunity to continue advising EPA and the SBAR panel regarding risk mitigation.

¹ 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, and provides forums for the advancement and promotion of the industry through educational and professional development services. 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 – EPA's Risk Evaluation and Assumptions

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.

(See p. 88, et. seq. Final Risk Evaluation, Jan. 2021)

For all 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 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." (See p. 91, et. seq., Draft Risk Assessment). (See p. 91, 95, 96, Final Risk Evaluation, Jan. 2021)

In March 2022, EPA revised the PV-29 risk evaluation, by publishing a revised Section 5, adopting the current administrations policies of a "whole chemical" approach and the assumption of no PPE when assessing risk. The new policies did not substantively change the risk evaluation. The new administration adopted and endorsed the Trump administration's flawed scientific reasoning when finalizing the current revised PV-29 evaluation. To comment on the whole chemical approach and assumption of no PPE, its necessary to briefly review the prior administration's findings.

In issuing the January 2021 final risk evaluation, mostly adopted by the current administration, EPA modified prior drafts due an interpretation of data from manufacturers submitted pursuant to a TSCA Section 4 test order. EPA explains that manufacturers 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. (See p. 53, Final Risk Evaluation, Jan. 2021)

EPA conducted further evaluation, with two signification 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.

(See p. 54-56, Final Risk Evaluation, Jan. 2021)

I. EPA's evaluation of workplace exposure and the assumption of no PPE unnecessarily focuses on the inadequacy of OSHA PEL's.

EPA's assumption of no PPE, when making a final risk determination, is based in part, on an assumption that OSHA's PELs are outdated. In EPA's view, it must evaluate an appropriate exposure level and appropriate level of PPE, without consideration of prior outdated practices. By doing so, EPA has not completely considered the body of legally enforceable exposure limits and controls, standard references and practices used by industrial hygienists when developing a safety program.

OSHA's website for PELs opens with a clear disclaimer that:

OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time.

The reason for this disclaimer is to alert industry that mere compliance with OSHA PELs does not meet legal obligations established under Section 5 of the *Occupational Safety and Health Act*, that is the "general duty clause:"

"Each employer . . . shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."

On the same OSHA PEL website, a few paragraphs below the opening statement, OSHA proceeds to explain that employers may need to refer to "alternate occupational exposure limits that may serve to better protect workers." OSHA recommends employers review limits of Cal OSHA, NIOSH (Recommended Exposure Limits), ACGIH (TLVs) and values established by foreign governments. Industrial hygienists commonly review these sources as well as AIHA (WEELs), limits established by the German government and others.

OSHA requires industry must take action if an individual could be exposed at the industry action level², usually set at half the PEL, but could potentially vary as determined by industrial hygienists consulting a variety of sources. The required action is determined on a case-by-case basis, due to the potential risk posed by use. The "industry action level" is enforceable. The attached OSHA citation notes an instance where a facility failed to establish a monitoring program at the action level to further evaluate exposures and determine appropriate safety measures.

Recognized bodies develop exposure levels that are largely uniform, creating a uniform understanding of workplace exposure. When an exposure limit diverges, industrial hygienists evaluate and discuss the value to understand reasons for divergence. EPA's risk evaluation methods pose grave concerns that it is developing methods and practices not generally accepted as sound science by the community of industrial hygienists. In effect, EPA is poised to derive exposure limits that are wildly divergent from those of recognized established bodies, undermining the agency's credibility. It also undermines the credibility of industry management when implementing safety programs, where management must justify its revisions to PPE based on EPA's determinations, potentially at odds with global norms.

If EPA has data to justify such a shift, it must engage with recognized authoritative bodies in industrial hygiene to review and contextualize the information as part of the risk evaluation process. Without closer alignment with standard methods, EPA's evaluations could undermine the field of industrial hygiene and credibility of the TSCA program, at a global level. Below you will find information about how the Trump Administration's PV-29 risk evaluation, as adopted and revised by the current administration, deviates from standard methods.

II. EPA's risk evaluation supports existing requirements 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 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

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 $^{^2}$ See p. vii for an explanation of the industry action level: https://www.cdc.gov/niosh/docs/76-131/pdfs/76-131.pdf

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. Prior to developing an ECEL, ACA recommends that the SBAR carefully consider risk mitigation strategies typically implemented 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. 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 implementing the GHS (U.N. Globally Harmonized System of Classification and Labelling of Chemicals). EPA references a European SDS as part of its hazard analysis at p. 65 of the Final Risk Evaluation. A U.S. Safety Data Sheet (SDS) from Sun Chemical, compliant with OSHA Haz Com, is attached hereto for reference.

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).

(p. 65, Final Risk Evaluation, Jan. 2021)

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" in Appendix A.4 of the OSHA Haz Com (29 CFR 1910.1200), referencing animal testing assays and threshold values for the substance in a mixture. PV29 does not meet the criteria for classification, as noted in 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 would consider OSHA requirements with the totality of information available, including a variety exposure levels, such as TLVs published by ACGIH, NIOSH recommended exposure levels, OSHA PELs, manufacturer determined levels, 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," at half of the reference airborne threshold concentration.

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 / m3, with monitoring methods, as noted in OSHA's Occupational Chemicals Database. Since EPA has not identified a toxicologically relevant exposure threshold, 5 mg/m3 should be the reference value for risk mitigation activities.

III. 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. 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.

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.

IV. The whole chemical approach to risk evaluation could result in a whole chemical approach to risk mitigation

The whole chemical approach could potentially compound the above noted flaws, by promoting a "one size fits all" approach to risk mitigation. In the case of PV-29, this involves assumptions of exposure to PV-29 dust, mischaracterized as a hazardous dust, including exposure to PV-29 nano-particles, at all levels of the value chain.

The whole chemical approach also could extend risk mitigation to conditions of use that typically do not pose an unreasonable risk, requiring costly and unnecessary PPE or other

workplace mitigation strategies. ACA is particularly concerned about the following statement from EPA,

Under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management options related to manufacture, processing, distribution in commerce, commercial use, and disposal in order to address the unreasonable risk.

(EPA, Revised Section 5 of the PV-29 Risk Evaluation, p. 1, March 2022)

The statement indicates a broad authority to regulate any condition of use, even those with no unreasonable risk, assuming a connection to conditions of use that cause risk. ACA is concerned that such an approach would only compound conservative assumptions leading to findings of unreasonable risk, to result in further conservative assumptions during risk mitigation. As noted above, the underlying hazard characterization and exposure assessment methodology of PV-29 is based on unwarranted assumptions.

Though not specifically an issue with PV-29, with other risk evaluations, EPA compounds flaws within each condition of use by relying on flawed exposure data, often substituting available exposure data of one product for another. Another compounding factor is the range of products under the umbrella of one condition of use. Often an outlying product, with a higher concentration of the chemical of concern, drives the risk evaluation for the entire condition of use.

During risk evaluation of the fist 10 chemicals, EPA provided a determination of confidence level for each condition of use, as a way of noting these flawed assumptions. However, EPA does not consider confidence level during risk mitigation. All conditions of use with an unreasonable risk finding are considered for a similar, if not same, risk mitigation approach.

ACA is concerned that these compounded flawed assumptions will now be used to create a nexus between conditions of use known to have no unreasonable risk to those with an unreasonable risk, under the "whole chemical" approach. EPA does not have the resources to analyze flawed assumptions and data affecting each condition of use to develop a nuanced risk mitigation strategy. The result would be a "whole chemical" approach to risk mitigation. ACA is concerned that the approach would not serve public safety or environmental protection and could undermine the agency's credibility.

V. Conclusion

The whole chemical approach and assumption of no PPE, though designed to increase accuracy of assessments by considering all conditions of use for risk mitigation, has potential to lead EPA to inaccurate conclusions, due to compounded assumptions, now carried into risk mitigation for all conditions of use. To increase accuracy, ACA recommends conducting future risk evaluations with engagement of industrial hygiene professionals and their representative organizations.

ACA also recommends careful consideration of all underlying data and limitations during the risk mitigation phase. This is especially important for PV-29 and others of the first ten chemicals, where evaluations are built on assumptions generally not used by industrial hygienists.

ACA appreciates the opportunity to comment on these matters. Please feel free to contact me if ACA can assist further in TSCA risk evaluation and/or risk mitigation processes.

Sincerely,

Riaz Zaman Sr. Counsel, Government Affairs American Coatings Association 901 New York Ave., Ste. 300 Washington, D.C. 20001 rzaman@paint.org 202-719-3715

U.S. Department of Labor Occupational Safety and Health Administration 500 Route 17 South 2nd Floor Hasbrouck Heights, NJ 07604



01/19/2022



Dear Employer:

Enclosed you will find citations for violations of the Occupational Safety and Health Act of 1970 (the Act) which may have accompanying proposed penalties. Also enclosed is a booklet entitled, "Employer Rights and Responsibilities Following an OSHA Inspection", (OSHA 3000-04R) revised 2018, which explains your rights and responsibilities under the Act. If you have any questions about the enclosed citations and penalties, I would welcome further discussions in person or by telephone. Please contact me at (201) 288-1700.

You will note on page 6 of the booklet that, for violations which you do not contest, you must (1) notify this office promptly by letter that you have taken appropriate corrective action within the time set forth on the citation; and (2) pay any penalties assessed. Please inform me of the abatement steps you have taken and of their dates together with adequate supporting documentation; e.g., drawings or photographs of corrected conditions, purchase/work orders related to abatement actions, air sampling results. This information will allow us to close the case.

As indicated on page 3 of the booklet, you may request an informal conference with me during the 15-workingday notice of contest period. During such an informal conference you may present any evidence or views which you believe would support an adjustment to the citation or the penalty.

If you are considering a request for an informal conference to discuss any issues related to this Citation and Notification of Penalty, you must take care to schedule it early enough to allow time to contest after the informal conference, should you decide to do so. Please keep in mind that a written letter of intent to contest must be submitted to the Area Director within 15 working days of your receipt of the citation. The running of this contest period is not interrupted by an informal conference.

If you decide to request an informal conference, please complete the attached notice at the bottom of this letter and post it next to the Citations as soon as the time, date and the place of the informal conference have been determined. Be sure to bring to the conference with you any and all supporting documentation of existing conditions as well as of any abatement steps taken thus far. If conditions warrant, we can enter into an informal settlement agreement which amicably resolves this matter without litigation or contest.

You should be aware that OSHA publishes information on its inspection and citation activity on the Internet under the provisions of Electronic Freedom of Information Act. The information related to these alleged violations will be posted when our system indicates that you have received this citation. You are encouraged to review the information concerning your establishment at www.osha.gov. If you have any dispute with the accuracy of the information displayed, please contact this office.

Sincerely,

for Lisa Levy Area Director

Enclosures

Occupational Safety and Health Administration 500 Route 17 South 2nd Floor Hasbrouck Heights, NJ 07604



Citation and Notification of Penalty

To:

Inspection Number:

Inspection Date(s): 08/04/2021 - 01/10/2022

Issuance Date: 01/19/2022

Inspection Site:

The violation(s) described in this Citation and Notification of Penalty is (are) alleged to have occurred on or about the day(s) the inspection was made unless otherwise indicated within the description given below.

This Citation and Notification of Penalty (this Citation) describes violations of the Occupational Safety and Health Act of 1970. The penalty(ies) listed herein is (are) based on these violations. You must abate the violations referred to in this Citation by the dates listed and pay the penalties proposed, unless within 15 working days (excluding weekends and Federal holidays) from your receipt of this Citation and Notification of Penalty **you either call to schedule an informal conference (see paragraph below) or** you mail a notice of contest to the U.S. Department of Labor Area Office at the address shown above. Please refer to the enclosed booklet (OSHA 3000) which outlines your rights and responsibilities and which should be read in conjunction with this form. Issuance of this Citation does not constitute a finding that a violation of the Act has occurred unless there is a failure to contest as provided for in the Act or, if contested, unless this Citation is affirmed by the Review Commission or a court.

Posting - The law requires that a copy of this Citation and Notification of Penalty be posted immediately in a prominent place at or near the location of the violation(s) cited herein, or, if it is not practicable because of the nature of the employer's operations, where it will be readily observable by all affected employees. This Citation must remain posted until the violation(s) cited herein has (have) been abated, or for 3 working days (excluding weekends and Federal holidays), whichever is longer.

Informal Conference - An informal conference is not required. However, if you wish to have such a conference you may request one with the Area Director during the 15 working day contest period by calling (201) 288-1700. During such an informal conference, you may present any evidence or views which you believe would support an adjustment to the citation(s) and/or penalty(ies).

If you are considering a request for an informal conference to discuss any issues related to this Citation and Notification of Penalty, you must take care to schedule it early enough to allow time to contest after the informal conference, should you decide to do so. Please keep in mind that a written letter of intent to contest must be submitted to the Area Director within 15 working days of your receipt of this Citation. The running of this contest period is not interrupted by an informal conference.

If you decide to request an informal conference, please complete, remove and post the Notice to Employees next to this Citation and Notification of Penalty as soon as the time, date, and place of the informal conference have been determined. Be sure to bring to the conference any and all supporting documentation of existing conditions as well as any abatement steps taken thus far. If conditions warrant, we can enter into an informal settlement agreement which amicably resolves this matter without litigation or contest.

Right to Contest — You have the right to contest this Citation and Notification of Penalty. You may contest all citation items or only individual items. You may also contest proposed penalties and/or abatement dates without contesting the underlying violations. <u>Unless you inform the Area Director in writing that you intend to contest the citation(s) and/or proposed penalty(ies) within 15 working days after receipt, the citation(s) and the proposed penalty(ies) will become a final order of the Occupational Safety and Health Review Commission and may not be reviewed by any court or agency.</u>

Penalty Payment – Penalties are due within 15 working days of receipt of this notification unless contested. (See the enclosed booklet and the additional information provided related to the Debt Collection Act of 1982.) Make your check or money order payable to "DOL-OSHA". Please indicate the Inspection Number on the remittance. You can also make your payment electronically at www.pay.gov. At the top of the pay.gov homepage, type "**OSHA**" in the Search field and select Search. From **OSHA Penalty Payment Form** search result, select Continue. The direct link is:

https://www.pay.gov/paygov/forms/formInstance.html?agencyFormId=53090334

You will be required to enter your inspection number when making the payment. Payments can be made by credit card or Automated Clearing House (ACH) using your banking information. Payments of \$25,000 or more require a Transaction ID, and also must be paid using ACH. If you require a Transaction ID, please contact the OSHA Debt Collection Team at (202) 693-2170.

OSHA does not agree to any restrictions or conditions or endorsements put on any check, money order, or electronic payment for less than the full amount due, and will process the payments as if these restrictions or conditions do not exist.

Notification of Corrective Action – For each violation which you do not contest, you must provide *abatement certification* to the Area Director of the OSHA office issuing the citation and identified above. This abatement certification is to be provided by letter within 10 calendar days after each abatement date. Abatement certification includes the date and method of abatement. If the citation indicates that the violation was corrected during the inspection, no abatement certification is required for that item. The abatement certification letter must be posted at the location where the violation appeared and the corrective action took place or employees must otherwise be effectively informed about abatement activities. A sample abatement certification letter is enclosed with this Citation. In addition, where the citation indicates that *abatement documentation* is necessary, evidence of the purchase or repair of equipment, photographs or video, receipts, training records, etc., verifying that abatement has occurred is required to be provided to the Area Director.

Employer Discrimination Unlawful – The law prohibits discrimination by an employer against an

employee for filing a complaint or for exercising any rights under this Act. An employee who believes that he/she has been discriminated against may file a complaint no later than 30 days after the discrimination occurred with the U.S. Department of Labor Area Office at the address shown above.

Employer Rights and Responsibilities – The enclosed booklet (OSHA 3000) outlines additional employer rights and responsibilities and should be read in conjunction with this notification.

Notice to Employees – The law gives an employee or his/her representative the opportunity to object to any abatement date set for a violation if he/she believes the date to be unreasonable. The contest must be mailed to the U.S. Department of Labor Area Office at the address shown above and postmarked within 15 working days (excluding weekends and Federal holidays) of the receipt by the employer of this Citation and Notification of Penalty.

Inspection Activity Data – You should be aware that OSHA publishes information on its inspection and citation activity on the Internet under the provisions of the Electronic Freedom of Information Act. The information related to these alleged violations will be posted when our system indicates that you have received this citation. You are encouraged to review the information concerning your establishment at www.osha.gov. If you have any dispute with the accuracy of the information displayed, please contact this office.

U.S. Department of Labor Occupational Safety and Health Administration



NOTICE TO EMPLOYEES OF INFORMAL CONFERENCE

An informal conference has been scheduled with OSHA to discuss the citation(s) is	sued on
01/19/2022. The conference will be held by telephone or at the OSHA office located	d at 500
Route 17 South, 2nd Floor, Hasbrouck Heights, NJ 07604 on	at
Employees and/or representatives of employees have a right	to attend an
informal conference	

CERTIFICATION OF CORRECTIVE ACTION WORKSHEET

Company Name: Inspection Site: Issuance Date: 01/19/2022	Inspection Number:
During Inspection" and return to: U.S.	For each item on this citation in this package that does not read "Corrected Department of Labor – Occupational Safety and Health 2nd Floor, Hasbrouck Heights, NJ 07604.
Citation Number and Item Num By (Method of Abatement):	ber was corrected on
Citation Number and Item Num By (Method of Abatement):	ber was corrected on
Citation Number and Item Num By (Method of Abatement):	ber was corrected on
Citation Number and Item Num By (Method of Abatement):	ber was corrected on
Citation Number and Item Num By (Method of Abatement):	ber was corrected on
Citation Number and Item Num By (Method of Abatement):	ber was corrected on
I certify that the information contained representatives have been informed of	in this document is accurate and that the affected employees and their the abatement.
Signature	Date
Typed or Printed Name	Title

NOTE: 29 USC 666(g) whoever knowingly makes any false statements, representation or certification in any application, record, plan or other documents filed or required to be maintained pursuant to the Act shall, upon conviction, be punished by a fine of not more than \$10,000 or by imprisonment of not more than 6 months or both.

POSTING: A copy of completed Corrective Action Worksheet should be posted for employee review

Occupational Safety and Health Administration

Inspection Number:

Inspection Date(s): 08/04/2021 - 01/10/2022

Issuance Date: 01/19/2022



Citation and Notification of Penalty

Company Name:	
Inspection Site:	

Citation 1 Item 1 Type of Violation: **Serious**

29 CFR 1910.1052(c)(1): Eight-hour time-weighted average (TWA) PEL. The employer shall ensure that no employee is exposed to an airborne concentration of MC in excess of twenty-five parts of MC per million parts of air (25 ppm) as an 8-hour TWA.

a) Extrusion Department, Hand Assembly Permaseal/Tube Assembly: On or about October 5, 2021, an assembly employee used Weldon 3, which contains 75 to 90% Methylene Chloride, to fuse the bottoms onto clear plastic cylindrical sections as part of the tube packaging manufacture process was exposed to 54 Parts Per Million (PPM) of Methylene Chloride over 8-hours with zero exposure averaged for any unsampled time.

ABATEMENT DOCUMENTATION REQUIRED FOR THIS ITEM

Occupational Safety and Health Administration

Inspection Number:

Issuance Date: 01/19/2022

- 01/10/2022



Citation and Notification of Penalty

Company Name:		

The alleged violations below have been grouped because they involve similar or related hazards that may increase the potential for injury or illness.

Citation 1 Item 2 a Type of Violation: **Serious**

29 CFR 1910.1052(d)(3): Where the initial determination showed employee exposures at or above the action limit or above the short term exposure limit, the employer did not establish a periodic exposure monitoring program for methylene chloride in accordance with Table 1:

a) Extrusion Department, Hand Assembly Permaseal/Tube Assembly: On or about August 4, 2021, the employer did not establish a periodic exposure monitoring program for assembly employees who used Weldon 3, which contains 75 to 90% Methylene Chloride, to fuse the bottoms onto clear plastic cylindrical sections as part of the tube packaging manufacture process. An employee was exposed to 54 Parts Per Million (PPM) of Methylene Chloride over 8-hours with zero exposure averaged for any unsampled time, which is over 2 times the OSHA Permissible Exposure Limit (PEL).

Establish a periodic exposure monitoring program for methylene chloride exposures which complies with Table 1. The employer may decrease the frequency of 8-hour TWA exposure monitoring to every six months when at least two consecutive measurements taken at least seven days apart show exposures to be at or below the 8-hour TWA PEL. The employer may discontinue the periodic 8-hour TWA monitoring for employees where at least two consecutive measurements taken at least seven days apart are below the action level. The employer may discontinue the periodic STEL monitoring for employees where at least two consecutive measurements taken at least 7 days apart are at or below the STEL.

ABATEMENT DOCUMENTATION REQUIRED FOR THIS ITEM

Occupational Safety and Health Administration

Inspection Number: Inspection Date(s): 08/04/2021 - 01/10/2022

Issuance Date: 01/19/2022



Citation and Notification of Penalty

Company Name:	
Inspection Site:	

<u>Citation 1 Item 2 b</u> Type of Violation: **Serious**

29 CFR 1910.1052(d)(4)(i): The employer shall perform exposure monitoring when a change in workplace conditions indicates that employee exposure may have increased. Examples of situations that may require additional monitoring include changes in production, process, control equipment, or work practices, or a leak, rupture, or other breakdown.

a) Extrusion Department, Hand Assembly Permaseal/Tube Assembly: On or about August 4, 2021, the employer had not monitored the exposure of assembly employees who used Weldon 3, which contains 75 to 90% Methylene Chloride, for several years, despite changes in workplace conditions, such as but not limited to an increase in the amount of Weldon -3 used and the hood used for ventilation in the area stopped working.

ABATEMENT DOCUMENTATION REQUIRED FOR THIS ITEM

Occupational Safety and Health Administration

Inspection Number:

Inspection Date(s): 08/04/2021 - 01/10/2022

Issuance Date: 01/19/2022



Citation and Notification of Penalty

Company Name:	
Inspection Site:	

<u>Citation 1 Item 3</u> Type of Violation: **Serious**

29 CFR 1910.1052(e)(1): The employer did not establish a regulated area wherever an employee's exposure to airborne concentrations of methylene chloride exceeded or could reasonably be expected to exceed either the 8-hour Time Weighted Average Permissible Exposure Limit or the Short Term Exposure Limit:

a) Extrusion Department, Hand Assembly Permaseal/Tube Assembly: On or about August 21, 2021, the employer notified employees that on August 10, 2021, the company had monitored the exposure of assembly employees who used Weldon 3, which contains 75 to 90% Methylene Chloride, and found that there had been an exposure at a Time Weighted Average of 86.6 PPM for the 8 hour period, which exceeded the OSHA PEL of 25 PPM as a Time Weighted Average, but did not establish a regulated area despite being aware that airborne concentrations of methylene chloride could reasonably be expected to exceed the 8 hour Time weighted hour Permissible Exposure Limit.

ABATEMENT DOCUMENTATION REQUIRED FOR THIS ITEM

Occupational Safety and Health Administration

Inspection Number:

Inspection Date(s): 08/04/2021 - 01/10/2022

Issuance Date: 01/19/2022



Citation and Notification of Penalty

Company Name:	
Inspection Site:	

Citation 1 Item 4 Type of Violation: **Serious**

29 CFR 1910.1052(f)(1): The employer did not institute and maintain the effectiveness of engineering controls and work practices to reduce employee exposure to or below the permissible exposure limits and wherever the feasible engineering controls and work practices which can be instituted were not sufficient to reduce employee exposure to or below the 8-hour time weighted average permissible exposure limit or short term exposure limit, the employer did not use them to reduce employee exposure to the lowest levels achievable and did not supplement them by the use of respiratory protection that compiled with the requirements of 29 CFR 1910.1052(g):

a) Extrusion Department, Hand Assembly Permaseal/Tube Assembly: On or about October 5, 2021, an assembly employee used Weldon 3, which contains 75 to 90% Methylene Chloride, to fuse the bottoms onto clear plastic cylindrical sections as part of the tube packaging manufacture process was exposed to 54 Parts Per Million (PPM) of Methylene Chloride over 8-hours with zero exposure averaged for any unsampled time. The employer did not institute engineering controls sufficient to reduce the employee's exposure below the OSHA's 8-hour Time Weighted Average Permissible Exposure Limit of 25 PPM and did not supplement them with the use of respiratory protection.

ABATEMENT DOCUMENTATION REQUIRED FOR THIS ITEM

Occupational Safety and Health Administration



Issuance Date: 01/19/202

- 01/10/2022



Citation and Notification of Penalty

Company Name:	

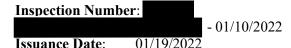
Citation 1 Item 5 Type of Violation: **Serious**

29 CFR 1910.1052(g)(1)(i): Respirators were not used during periods when an employee's exposure to methylene chloride exceeds the 8-hour time weighted average permissible exposure limit or short term exposure limit:

a) Extrusion Department, Hand Assembly Permaseal AKA Tube Assembly: On or about October 5, 2021, an assembly employee used Weldon 3, which contains 75 to 90% Methylene Chloride, to fuse the bottoms onto clear plastic cylindrical sections as part of the tube packaging manufacture process and was exposed to 54 Parts Per Million (PPM) of Methylene Chloride over 8-hours with zero exposure averaged for any unsampled time. The employer did not provide and require use of respiratory protection to reduce the employee's exposure below the OSHA's 8-hour Time Weighted Average Permissible Exposure Limit of 25 PPM.

ABATEMENT DOCUMENTATION REQUIRED FOR THIS ITEM

Occupational Safety and Health Administration





Citation and Notification of Penalty

Company Name:			
Inspection Site:			

Citation 1 Item 6 Type of Violation: **Serious**

29 CFR 1910.1052(h)(1): Where needed to prevent MC-induced skin or eye irritation, the employer shall provide clean protective clothing and equipment which is resistant to MC, at no cost to the employee, and shall ensure that each affected employee uses it. Eye and face protection shall meet the requirements of 29 CFR 1910.133 or 29 CFR 1915.153, as applicable.

a) Extrusion Department, Hand Assembly Permaseal/Tube Assembly: On or about August 4, 2021, assembly employees used Weldon 3, which contains 75 to 90% Methylene Chloride, to fuse the bottoms onto clear plastic cylindrical sections as part of the tube packaging manufacture process. The employees pour the Weldon 3, which is a liquid, from the one gallon container into smaller bottles, then used the smaller bottles to deliver the product to a shallow container into which the tube is dipped so the cap could be fused with it. The employer did not provide and require use of aprons, impervious gloves, eye and face protection to reduce the employee's exposure.

ABATEMENT DOCUMENTATION REQUIRED FOR THIS ITEM

Occupational Safety and Health Administration

Inspection Number:
Inspection Date(s): - 01/10/2022
Issuance Date: 01/19/2022



Citation and Notification of Penalty

Company Name:		
Inspection Site:		

Citation 1 Item 7 Type of Violation: **Serious**

29 CFR 1910.1052(i)(2): If it is reasonably foreseeable that an employee's eyes may contact solutions containing 0.1 percent or greater MC (for example through splashes, spills or improper work practices), the employer shall provide appropriate eyewash facilities within the immediate work area for emergency use, and shall ensure that affected employees use those facilities when necessary.

a) Extrusion Department, Hand Assembly Permaseal/Tube Assembly: On or about August 4, 2021, assembly employees used Weldon 3, which contains 75 to 90% Methylene Chloride, to fuse the bottoms onto clear plastic cylindrical sections as part of the tube packaging manufacture process and transferred the Weldon 3 from gallon containers, by pouring it into smaller containers without using eye protection. The employer did not provide an eyewash in the immediate work area. The nearest eyewash was about a hundred feet away and the path was blocked by racks of materials.

Date By Which Violation Must be Abated: Corrected During Inspection Proposed Penalty: \$10,360.00

Occupational Safety and Health Administration

Inspection Number:

Inspection Date(s): 08/04/2021 - 01/10/2022**Issuance Date**: 01/19/2022



Citation and Notification of Penalty

Company Name:	
Inspection Site:	

Citation 1 Item 8 Type of Violation: **Serious**

29 CFR 1910.1052(j)(1)(i): The employer did not make medical surveillance available for employees who were or potentially were exposed to methylene chloride at or above the action level on 30 or more days per year, or above the 8-hour time weighted average permissible exposure limit or the short term exposure limit on 10 or more days per year:

a) Extrusion Department, Hand Assembly Permaseal AKA Tube Assembly: On or about October 5, 2021, assembly employees used Weldon 3, which contains 75 to 90% Methylene Chloride, to fuse the bottoms onto clear plastic cylindrical sections as part of the tube packaging manufacture process. The employer did not make medical surveillance available to employees who were or were potentially exposed at or above the action level on 30 or more days per year.

ABATEMENT DOCUMENTATION REQUIRED FOR THIS ITEM

Occupational Safety and Health Administration

Inspection Number: Inspection Date(s): 08/04/2021 - 01/10/2022

Issuance Date: 01/19/2022



Citation and Notification of Penalty

Company Name:		

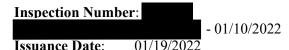
<u>Citation 1 Item 9</u> Type of Violation: **Serious**

29 CFR 1910.1052(l)(1): The employer shall provide information and training for each affected employee prior to or at the time of initial assignment to a job involving potential exposure to MC.

a) Extrusion Department, Hand Assembly Permaseal/Tube Assembly: On or about August 4, 2021, assembly employees used Weldon 3, which contains 75 to 90% Methylene Chloride, to fuse the bottoms onto clear plastic cylindrical sections as part of the tube packaging manufacture process. The employer did not provide training to employees who are doing tube assembly with Weldon 3 prior to initial assignment.

ABATEMENT DOCUMENTATION REQUIRED FOR THIS ITEM

Occupational Safety and Health Administration





Citation and Notification of Penalty

Company Name:		
Inspection Site:		

Citation 2 Item 1 Type of Violation: **Other-than-Serious**

29 CFR 1910.1052(d)(5)(ii): When monitoring results indicated that employee exposure was above the eight hour time weighted average (TWA) permissible exposure limit (PEL) or the short term exposure limit (STEL), the employer did not describe in the written notification the corrective action being taken to reduce employee exposure to or below the eight hour TWA PEL or STEL and/or the schedule for completion of this action:

- a) Extrusion Department, Hand Assembly Permaseal/Tube Assembly: On or about August 21, 2021, the employer notified employees that on August 10, 2021, the company had monitored the exposure of assembly employees who used Weldon 3, which contains 75 to 90% Methylene Chloride, and found that there had been an exposure at a Time Weighted Average of 86.6 PPM for the 8 hour period, which exceeded the OSHA PEL of 25 PPM as a Time Weighted Average, but did not describe the corrective action being taken to reduce employee exposure below the TWA PEL and did not include a schedule for completion of this action.
- b) Extrusion Department, Hand Assembly Permaseal/Tube Assembly: On or about September 7, 2021, the employer notified employees that on August 26, 2021, the company had monitored the exposure of assembly employees who used Weldon 3, which contains 75 to 90% Methylene Chloride, and found that there had been an exposure at a Time Weighted Average of 43.1 PPM for the 8 hour period, which exceeded the OSHA PEL of 25 PPM as a Time Weighted Average, but did not describe the corrective action being taken to reduce employee exposure below the TWA PEL and did not include a schedule for completion of this action.
- c) Extrusion Department, Hand Assembly Permaseal/Tube Assembly: On or about October 15, 2021, the employer notified employees that on October 5, 2021, the company had monitored the exposure of assembly employees who used Weldon 3, which contains 75 to 90% Methylene Chloride, and found that there had been an exposure at a Time Weighted Average of 46.9 PPM for the 8 hour period, which exceeded the OSHA PEL of 25 PPM as a Time Weighted Average, but did not describe the corrective action being taken to reduce employee exposure below the TWA PEL and did not include a schedule for completion of this action.

ABATEMENT DOCUMENTATION REQUIRED FOR THIS ITEM

Date By Which Violation Must be Abated: Proposed Penalty:

February 22, 2022 \$1,163.00

See pages 1 through 4 of this Citation and Notification of Penalty for information on employer and employee rights and responsibilities.

for Lisa Levy
Area Director

U.S. Department of Labor

Occupational Safety and Health Administration 500 Route 17 South 2nd Floor Hasbrouck Heights, NJ 07604



INVOICE / DEBT COLLECTION NOTICE

Company Name:

Issuance Date: 01/19/2022

Summary of Penalties for Inspection Number: 1547193

Citation 1 Item 1, Serious \$14,502.00
Citation 1 Item 2a, Serious \$14,502.00
Citation 1 Item 2b, Serious \$0.00

Citation 1 Item 3, Serious	\$14,502.00
Citation 1 Item 4, Serious	\$14,502.00
Citation 1 Item 5, Serious	\$14,502.00
Citation 1 Item 6, Serious	\$14,502.00
Citation 1 Item 7, Serious	\$10,360.00
Citation 1 Item 8, Serious	\$14,502.00
Citation 1 Item 9, Serious	\$14,502.00
Citation 2 Item 1, Other-than-Serious	\$1,163.00

TOTAL PROPOSED PENALTIES:

\$127,539.00

To avoid additional charges, please remit payment promptly to this Area Office for the total amount of the uncontested penalties summarized above. Make your check or money order payable to: "DOL-OSHA". Please indicate OSHA's Inspection Number (indicated above) on the remittance. You can also make your payment electronically at www.pay.gov. At the top of the pay.gov homepage, type "OSHA" in the Search field and select Search. From the OSHA Penalty Payment Form search result, select Continue. The direct link is: https://www.pay.gov/paygov/forms/formInstance.html?agencyFormId=53090334. You will be required to enter your inspection number when making the payment. Payments can be made by credit card or Automated Clearing House (ACH) using your banking information. Payments of \$25,000 or more require a Transaction ID, and also must be paid using ACH. If you require a Transaction ID, please contact the OSHA Debt Collection Team at (202) 693-2170.

OSHA does not agree to any restrictions or conditions or endorsements put on any check, money order, or electronic payment for less than the full amount due, and will cash the check or money order as if these restrictions or conditions do not exist.

If a personal check is issued, it will be converted into an electronic fund transfer (EFT). This means that our bank will copy your check and use the account information on it to electronically debit your account for the amount of the check. The debit from your account will then usually occur within 24 hours and will be shown on your regular account statement. You will not receive your original check back. The bank will destroy your original check, but will keep a copy of it. If the EFT cannot be completed because of insufficient funds or closed account, the bank will attempt to make the transfer up to two times.

Pursuant to the Debt Collection Act of 1982 (Public Law 97-365) and regulations of the U.S. Department of Labor (29 CFR Part 20), the Occupational Safety and Health Administration is required to assess interest, delinquent charges, and administrative costs for the collection of delinquent penalty debts for violations of the Occupational Safety and Health Act.

<u>Interest</u>: Interest charges will be assessed at an annual rate determined by the Secretary of the Treasury on all penalty debt amounts not paid within one month (30 calendar days) of the date on which the debt amount becomes due and payable (penalty due date). The current interest rate is one percent (1%). Interest will accrue from the date on which the penalty amounts (as proposed or adjusted) become a final order of the Occupational Safety and Health Review Commission (that is, 15 working days from your receipt of the Citation and Notification of Penalty), unless you file a notice of contest. Interest charges will be waived if the full amount owed is paid within 30 calendar days of the final order.

<u>Delinquent Charges</u>: A debt is considered delinquent if it has not been paid within one month (30 calendar days) of the penalty due date or if a satisfactory payment arrangement has not been made. If the debt remains delinquent for more than 90 calendar days, a delinquent charge of six percent (6%) per annum will be assessed accruing from the

Administrative Costs: Agencies of the Department of Labor are required to assess additional charges for the recovery of delinquent debts. These additional charges are administrative costs incurred by the Agency in its attempt to collect an unpaid debt. Administrative costs will be assessed for demand letters sent in an attempt to collect the unpaid debt.

Rich	01/19/2022
for Lisa Levy	Date
Area Director	

date that the debt became delinquent.