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VIA WWW.REGULATIONS.GOV

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Gabriela Rossner
Existing Chemicals Risk Management Division
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Re: Comments on EPA's Proposed Trichloroethylene (TCE) Regulation under the Toxic Substances Control Act (TSCA), Docket No. EPA-HQ-OPPT-2020-0642

Dear Ms. Rossner:

PPG appreciates the opportunity to submit these comments on EPA's Proposed TCE Regulation under the Toxic Substances Control Act (TSCA)**, (**Proposed Rule). As described in these comments, PPG requests that EPA include in the final TCE risk management rule, the Section 6(g) exemption for the manufacturing of PPG's TESLIN® substrate, a specialty polymeric microporous sheet material, as described in PPG's TSCA Section 6(g) Exemption Request, June 29, 2023, and without restricting any applications of *Teslin* substrate.[1] We also request that EPA withdraw both proposed ECELs, because as described in detail in Appendices A, B and C, neither ECEL reflects either the best available science or the weight of the scientific evidence, as required under TSCA Section 26.[2] EPA has also failed to adequately justify its proposed ban on disposal of TCE in wastewater.

These comments also offer potential options that PPG is considering to further reduce occupational exposures during the manufacture of *Teslin* substrate from levels that are already nearly two-orders of magnitude below the OSHA Permissible Exposure Limit (PEL) of 100 ppm.

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[1]. The exemption request is reference 67 in the Proposed Rule, 88 Fed. Reg. 74712, 74780 (Oct. 31, 2023). The exemption request is identified by Document ID EPA-HQ-OPPT-2020-0642-0098 within the Docket for the Proposed Rule ("Exemption Request"), *available at* https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0642-0098.

[2] *See* 15 U.S.C. § 2625(h) ("[T]o the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science."); *see also id.* at § 2625(i) ("The Administrator shall make decisions … based on the weight of the scientific evidence.").

I. PPG's 6(g) Exemption Should Be Incorporated Into EPA's Final Regulatory Action

TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, in 2016, authorizes EPA to exempt specific conditions of use from otherwise applicable risk management requirements. Importantly, Section 6(g) provides three criteria, as specified in subsections (1)(A), (B), and (C), any of which can support an exemption request. In granting an exemption, TSCA requires EPA to impose conditions, (e.g., monitoring, reporting requirements) to "protect health and the environment," but those conditions cannot impede "achieving the purposes of the exemption."[3] In adopting Section 6(g)((4), Congress recognized that, "by its nature, an exemption will allow for activities that present some degree of unreasonable risk."[4]

In its exemption request of June 29, 2023, PPG relied on subsections (A) and (B), and we are pleased that in the Proposed Rule, EPA preliminarily agrees with PPG's reliance on and rationale for these subsections. EPA includes PPG's 6(g) exemption in the primary alternative action, and by doing so EPA affirms that PPG has fully met the 6(g) exemption criteria. We, therefore, request that in the final TCE risk management regulation, EPA explicitly include this 6(g) exemption, without limiting the applications of *Teslin* substrate to EPA's proscriptive list.[5]

A. EPA Should Grant PPG's 6(g) Exemption Request Without Restricting *Teslin* Substrate's Applications

In "grant[ing] an exemption from a requirement of a subsection (a) rule for a specific condition of use of a chemical substance or mixture," EPA must find that "the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure."[6] With respect to PPG's exemption request, the particular condition of use is the industrial and commercial use of TCE as a processing aid for specialty polymeric microporous sheet materials (*Teslin* substrate). As noted, EPA preliminarily granted the exemption as part of the proposed primary alternative regulatory action.

Importantly, the plain language of TSCA Section 6(g)(A) makes clear that the criticality and essentiality of the "use" refers to the use of TCE, ***not*** the use of the end product, namely *Teslin* substrate. As discussed in PPG's exemption request, TCE is essential to the production of *Teslin* substrate because TCE possesses "a unique combination of chemical properties that, together, facilitate the controlled removal of process oil required in order to achieve a microporous film […]."[7] PPG, of course, readily acknowledges in its exemption request, and as underscored by EPA in the Proposed Rule, that *Teslin* substrate is a critical and essential component in a wide range of products used in everyday life, (e.g., passports, e-passports,

[3] 15 U.S.C. § 2605(g)(4).

[4] 162 Cong. Rec. S3511-01, at *S3517.

[5] 88 Fed. Reg. at 74757.

[6] 15 U.S.C. § 2605(g)(1)(A).

[7] *See*, Exemption Request at 4.

labels for chemical drums, complex filtration elements and cartridges). But these critical and essential uses are not the condition of use of TCE that is the very basis for the exemption.

Section 6(g)(4) authorizes EPA to impose conditions on the exempted condition of use as "necessary to protect health and the environment while achieving the purposes of the exemption." But this authority does not extend to *Teslin* substrate, only the industrial and commercial use of TCE as a processing aid for the manufacture of *Teslin* substrate.

Moreover, restricting *Teslin* substrate applications to a subset of the comprehensive applications that were included in PPG's exemption request likely would render the entire *Teslin* substrate manufacturing process uneconomical, leading to closure of the only facility in the world manufacturing *Teslin* substrate, or at a minimum, forcing PPG to drastically cut capacity, preventing the business from supplying the applications that EPA has recognized as being critical and essential.[8]

B. EPA Has Not Justified its Proposed Ban of TCE Disposal to Industrial Pre-Treatment, Industrial Treatment, or Publicly Owned Treatment Works

EPA proposes to ban the disposal of TCE to industrial wastewater pretreatment and treatment, and to publicly owned treatment works (POTW), regardless of the concentration of TCE in wastewater or the amount of frequency of wastewater discharge. According to EPA, a ban is necessary to eliminate the unreasonable risk to workers. Yet, EPA's failure to provide justification for this draconian prohibition cannot be reconciled with TSCA's requirement to eliminate unreasonable risk "to the extent necessary."[9] And as discussed blow, unreasonable risk cannot mean "any risk."

Moreover, TSCA section 9 (b) explicitly mandates that EPA coordinate actions under TSCA "with actions taken under other Federal laws administered in whole or in part by the Administrator."[10] But EPA provides no indication that any coordination has taken place. EPA dismisses the utility of the Clean Water Act (CWA) in eliminating or reducing risk to a sufficient extent by stating that the timing of updating CWA regulations "cannot be estimated," and that the CWA does not address worker exposures.[11] None of these explanations, however, addresses why TCE levels in wastewater, if shown to present unreasonable risk, cannot be reduced through regulatory actions under the CWA, rather than TSCA.

Importantly, the TCE levels in PPG's cooling tower blowdown water, before it is discharged into a POTW, are vanishingly small. The most recent sampling data on TCE levels were either non-detect or no higher than approximately 1 ppb. After discharge into a POTW, these

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[8] *See*, 88 Fed. Reg. at 74757.

[9] 15 U.S.C. § 2605(a).

[10] *Id.* at § 2608(b).

[11] 88 Fed. Reg. at 74774.

levels would necessarily drop further due to converging flows coming from other areas of the PPG plant. Thus, these levels, even if detectable, do not present unreasonable risk.

C. EPA Must Ensure that Sufficient TCE Remains Available for Section 6(g) Exemptions

A Section 6(g) exemption for PPG's continued use of TCE for *Teslin* substrate manufacturing will become a *de facto* prohibition if a final TCE risk management rule does not ensure access to multiple sources of TCE for the duration of the exemption period of 15 years. As underscored in PPG's exemption request, "one of two domestic suppliers stopped manufacturing TCE in late 2021."[12] The Proposed Rule provides little assurance that TCE will remain available. EPA merely concludes "based on information received through stakeholder engagement and professional judgment, that there would remain a sufficient supply of TCE in circulation […]."[13] EPA must buttress its conclusion with reliable estimates and assurances of TCE's availability after the final rule is issued, so as to ensure the viability of PPG's exemption (as well as other Section 6(g) exemptions) throughout the exemption periods.

II. The Proposed ECELs are Orders of Magnitude Below Any "Unreasonable Risk of Injury to Health"

In the final TCE risk evaluation, EPA determined that most of the conditions of use present "unreasonable risk of injury to health or the environment," which then triggered the development of the Proposed Rule to eliminate unreasonable risk "to the extent necessary."[14] Thus, knowing what is and isn't unreasonable risk would seem to be fundamental to proposing risk management measures. Yet, TSCA does not define unreasonable risk.[15] Although in amending TSCA in 2016,

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[12] Exemption Request at 3.

[13] 88 Fed. Reg. 74716.

[14] *See* U.S. EPA, *Risk Evaluation for Trichloroethylene*, EPA Document #740R18008 (November 2020) ("TCE Risk Evaluation), *available at* https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0642-0036.

[15] In finalizing the rule on procedures for chemical risk evaluation under TSCA, EPA could have defined the term "unreasonable risk," but like Congress, it opted not to. Instead, EPA delineated a list of "relevant factors" it will consider it making an unreasonable risk determination, including the following:

> The effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any susceptible populations), the severity of hazard (the nature of the hazard, the irreversibility of hazard), and uncertainties.

82 Fed. Reg. 33726, 33735 (July 20, 2017).

Congress did not include a definition, there is legislative history that defines what is and is not unreasonable risk:

> [U]nreasonable risk under the conditions of use [is] the safety standard to be applied by EPA. 'Unreasonable risk' does not mean no risk; it means that EPA must determine, on a case-by-case basis, whether the risks posed by a specific high priority substance are reasonable in the circumstances of exposure and use.[16]

Thus, a no "unreasonable risk" determination cannot equate to a finding of no risk, and an "unreasonable risk" determination must mean that there exists risk that is deemed to be reasonable. The proposed existing chemical exposure limits (ECELs), however, conflict with Congress's intent.

The Proposed Rule proposes two ECELs, the lowest ECEL, 0.0011 ppm, based on developmental toxicity (fetal cardiac defects), and an alternative ECEL 0.0040 ppm, based on the immunotoxicity endpoint. According to EPA, ensuring that exposure levels remain at or below these values will eliminate unreasonable risk. But "the ECELs that EPA [] has proposed as risk management measures in the proposed TSCA TCE Rule **are orders of magnitude below levels where effects have been observed in humans and are comparable to background residential indoor air concentrations,**"[17] and far below any real "risk of injury." Thus, the ECELs cannot lawfully be interpreted as a means to eliminate unreasonable risk "to the extent necessary," pursuant to TSCA section 6 and utterly fail to reflect Congressional intent as to what constitutes "unreasonable risk."

It is little wonder why EPA acknowledges in the Proposed Rule that the ECELs are not only unattainable in any occupational environment but are also unmeasurable.[18] No current accepted and approved Industrial Hygiene (IH) sampling and analytical technique can achieve a detection or limit of quantification at or below the proposed ECEL.[19] Sampling technologies, such as EPA Method TO-15 and TO-17, are proven technologies but are not tested or approved for full shift

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But these factors are largely unhelpful in understanding quantitatively the confines of unreasonable risk.

TSCA also fails to furnish a definition of "injury," but elsewhere, EPA borrows the term from "OSHA regulations regarding employee injury and illness logs. EPA interprets the term 'injury' to include any effect on a human from a release of a regulated substance that requires medical treatment or hospitalization. Medical treatment includes any treatment, other than first aid, administered by a doctor or registered personnel under the supervision of a doctor (see definitions 40 CFR §68.3)." *See* https://www.epa.gov/rmp/what-definition-injury

[16] 162 Cong. Rec. S3511-01, at *S3522

[17] See Appendix B.

[18] *See* 88 Fed. Reg. at 33735.

[19] In response to EPA's request for comment 19 and 32, 88 Fed. Reg. at 74777.

industrial hygiene exposure sampling. Direct reading technologies such as PID or FTIR could have VOC interferences that would overestimate the exposure, and typically have accuracy of + or – 35%.[20]

A. Having Rejected the Fetal Cardiac Defects Endpoint as the Basis for Unreasonable Risk Determinations in the Final Risk Evaluation, EPA Cannot Lawfully Rely on that Same Endpoint in Proposing an ECEL of 0.0011 ppm

In EPA's final TCE risk evaluation, EPA evaluated fetal cardiac defects as a potential endpoint for risk conclusions, but ultimately, and unequivocally, "concluded that acute immunosuppression and chronic autoimmunity were the best overall non-cancer endpoints for use in Risk Evaluation under TSCA, **based on the best available science and weight of the scientific evidence, and were used as the basis of risk conclusions** […]."[21]

In the Proposed Rule, however, EPA now jettisons that conclusion without any rational scientific explanation. Instead, EPA raises the ominous specter of "political interference and scientific integrity," and astonishingly references "focused attention on this [fetal cardiac defects] issue from the SACC [Science Advisory Committee on Chemicals] and public commenters reacting to the draft Risk Evaluation for TCE." But none of this is relevant because in finalizing the TCE risk evaluation, EPA considered **all of these comments before rejecting fetal cardiac defects** as the basis of EPA's risk conclusions. Moreover, EPA's about-face cannot lawfully be reconciled with the substantial evidence standard required under TSCA.[22]

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[20] See, Comments submitted by the American Chemistry Council (ACC Comments). Also, the technological feasibility of IH sampling and analysis limitations apply equally to establishing an action level, in order to enable compliance.

[21] TCE Risk Evaluation, at 280 (emphasis added).

[22] *See* 15 U.S.C. § 2618(c) (setting forth TSCA's "substantial evidence" standard of review). Congress intended for courts under Section 19's "substantial evidence" standard to "engage in a *searching review* of [EPA's] reasons and explanations for [its] conclusions" (emphasis in original). *Chem. Mfrs. Ass'n v. EPA*, 859 F.2d 977, 991 (D.C. Cir. 1988) ("*CMA*"), (emphasis in original). Citing to TSCA's legislative history, *CMA* held that this standard is a "demanding one" and it is more "rigorous" than the deferential "arbitrary and capricious" review typically applied in APA cases. *Id.* at 991-992. The Court must ensure EPA has "identif[ied] the facts that underlie its determination" and that its action is "supported by [the] record" taken as a whole. *Id.* at 992. As always, the Court cannot substitute its own judgment for that of EPA. *Id.*

B. Neither ECEL Represents the Best Available Science or the Weight of the Scientific Evidence

Even if EPA could resurrect the fetal cardiac defects as the basis for the proposed ECEL of 0.0011 ppm, as made abundantly clear in Appendices A-C, neither ECEL represents the best available science or the weight of the scientific evidence, as mandated by TSCA section 26. As described more fully in these Appendices:

- In sum, the ECELs proposed in the EPA (2023) TCE Risk Management Rule are unreasonable and unjustifiable because the analysis and conclusions of the EPA (2020) Risk Evaluation are not based on the best available science as required by statute and defined in the pertinent guidance. Specifically, EPA (2020) failed to provide a competent, transparent, unassailably unbiased review and evaluation of the relevant scientific studies and thoughtful, comprehensive responses to (and substantive re-evaluations and revisions in response to) critical comments on vital issues from the SACC and other reviewers. Ultimately, EPA's failure to select critical endpoints and perform dose-response assessments in a defensible and transparent manner resulted in proposed and primary alternative ECELs, as specified in the EPA (2023) Proposed Risk Management Rule, which are unreasonable, unjustifiable and unacceptable.[23]

- The basis of the proposed TCE ECELs — and by extension the WCPP conditions — do not reflect the best available science and do not comply with EPA's statutory requirements under TSCA. In addition, they contradict the recommendations of EPA's TSCA Science Advisory Committee on Chemicals (SACC, 2020), and even contradict the EPA's own determinations described in their TSCA TCE risk evaluation. The EPA's TCE ECELs are inconsistent with basic principles of toxicology and risk assessment, as well as the published literature on TCE toxicology and epidemiology. Given the questions of reliability, completeness and transparency surrounding the TCE Risk Evaluation, the extraordinary uncertainty inherent to the ECELs, and the inevitability that this proposed Rule will cripple the sectors that EPA acknowledges are critical to the US economy, national security, and infrastructure, it is entirely inappropriate to impose the proposed exposure levels on the battery separator or other exempt manufacturing sectors at this time.[24]

- Taken together, the fetal cardiac and autoimmune endpoints that form the basis of US EPA's Proposed ECEL (0.0011 ppm) and Primary Alternative ECEL (0.004 ppm), respectively, are highly uncertain due to a number of critical issues, many of which have been previously acknowledged by US EPA and/or identified by various expert panels, including the SACC. Overall, these endpoints lack reproducibility across studies, suffer from serious flaws in study design and data analysis, or have not been found to be clearly adverse. As a result of these and other issues, US EPA's use of the

[23] See Appendix A.

[24] See Appendix B.

fetal cardiac and autoimmune endpoints for derivation of TCE ECELs is not scientifically appropriate, particularly for critical and exempt uses, since US EPA has acknowledged in the Proposed Risk Management Rule that meeting these ECELs will be challenging and generally not achievable. It is our recommendation that US EPA re-evaluate its use of these endpoints as the basis of their proposed ECELs.[25]

III. PPG's EHS and IH Processes are Protective and Conservative

A. Proactive Industrial Hygiene

PPG has been proactive in Industrial Hygiene (IH) since the 1930s. In the 1930s, IH consultants visited PPG plants, and PPG joined the Industrial Health Foundation. In the 1950s, plant safety rules were created to prevent dust exposure. In the 1960s, full-time industrial hygienists were hired. In the 1970s, the corporate occupational health policy manual, IH training for new EHS site managers, and routine industrial hygiene sampling programs were established. In the 1980s, business division level IH staff expanded and corporate compliance assurance included occupational health audits. In the 2000s, the business division IH staff merged into Corporate EHS function, IH sampling training course was revised and deployed globally, and the global PPG EHS Management System was defined, and included IH.

The PPG EHS Policy requires that employees be provided with a safe and healthful workplace. Part of the PPG IH process includes exposure risk determinations and comparing airborne workplace levels to allowable exposure limits.

PPG's IH Process has been developed to enable PPG facilities to properly manage occupational health risks in their operations associated with potential exposure to chemical, physical, and biological agents. This process is designed to aid all units to effectively anticipate, recognize, evaluate, communicate and control such potential health hazards in the workplace in order to prevent occupational illness and disease.

As part of its EHS management system, PPG has a global corporate requirement document: Industrial Hygiene, Exposure Assessment Requirement, and each PPG location is internally audited for compliance assurance. Potential occupational exposures to chemical and physical hazards must be assessed to ensure a safe work environment and to comply with certain government regulations. An IH exposure assessment program is implemented at PPG locations when a hazard and/or qualitative risk assessment indicates employee exposure may exceed applicable exposure limits. The results of the IH exposure assessments are used to determine the need for risk control programs to reduce employee exposure to chemical and physical hazards.

Key requirements for *each* PPG location include:

1. A hazard and/or qualitative risk assessment is completed to determine which operations pose a risk for employee exposure to chemical and physical hazards.

[25] See Appendix C.

2. An annual IH sampling plan is prepared based on the hazard and/or risk assessment and completed by year end.
3. IH sampling is performed by trained individuals or contractors using approved methodology, maintained and calibrated equipment.
4. IH samples are analyzed in approved and/or accredited laboratories.
5. IH sampling results are communicated to employees and maintained in the corporate IH database.
6. IH overexposures are investigated to identify causes and corrective actions.
7. IH exposure data are summarized and reviewed at least annually to determine changes in the applicability of medical exams, training and exposure controls.

The source of the PPG occupational exposure limits per region are the lowest of either the national or regional regulatory limits, PPG Internal PEL (IPELs), or American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs®). PPG IPELS include: 8-hour Time Weighted Averages (TWA), 15-minute Short Term Exposure Limits (STEL), and sometimes instantaneous or ceiling limits. The annual update of the PPG IPEL list includes review of revised ACGIH TLV® exposure levels by the IPEL committee for consideration of adoption. (See Appendix D)

For those IPELs that are adopted from another company's exposure limit or from a regulatory agency, the Safety Data Sheet (SDS) or regulatory documentation needs to be obtained and included as part of the PPG documentation. The recommendation regarding the IPEL will be forwarded to the chair of the PPG Occupational Health Council (OHC) who will place the recommendation on the agenda for consideration at the next OHC meeting. The IPEL Committee will simultaneously inform the Chair of the Product Stewardship Council that it has forwarded an IPEL recommendation to the OHC.

For TCE, PPG currently has an IPEL of 5 ppm for a full shift 8-hour time weighted average (TWA) and 25 ppm for a 15-minute short term exposure limit (STEL). The PPG IPEL of 5 ppm, which was adopted from another company's recommended exposure limit, is 5% of the federal Occupational Safety and Health Administration (OSHA) PEL, 25% of the California OSHA PEL, and 50% of the ACGIH TLV®.[26] The PPG STEL of 25 ppm, which was adopted from the ACGIH STEL, is 12.5% of the lowest OSHA ceiling limit of 200 ppm.

B. Medical Screening Examinations are Complementary to IH Exposure Evaluations and are the Foundation of Effective Occupational Health Programs

PPG uses medical surveillance programs, as a required part of the EHS management system to prevent harm through detection and elimination of underlying causes of chemical and physical

[26] See ACC Comments.

hazards, through detection of harmful trends in groups of workers with similar exposure patterns.[27]

Occupational medical surveillance examinations, if properly designed and conducted, will fulfill the following purposes:

- Establish a baseline for future surveillance.
- Document pre-existing conditions.
- Determine suitability for the job.
- Form the basis for advice to management on workplace accommodations and activity restrictions for individuals with impairments or specific susceptibilities.
- Diminish the potential for an adverse impact by the job on health.
- Prevent disease by addressing risk factors - primary prevention.
- Detect disease before symptoms appear - secondary prevention.

Multiple PPG occupational medical professionals, including our medical director, recommend initiating a medical surveillance for those in the similar exposure group with potential for exposure above the established action level, including an annual medical records review and liver and kidney function tests.

C. PPG has IH Processes and Procedural Controls to Reduce Release of TCE in the Production of *Teslin* Substrate at the Barberton, Ohio Facility

As noted, the PPG site in Barberton, Ohio produces *Teslin* substrate, with potential for worker exposure to TCE vapors. PPG's current process has a fully enclosed and negatively pressurized extractor/dryer/oven area of the process during normal operation.[28] All TCE process vapors are contained and transported through the carbon bed filtration system during normal operations. However, non-routine activities may necessitate worker access into the extractor/dryer area, which releases TCE vapors into the occupied area. These non-routine activities require workers in the vicinity of this area to wear full-face respirators with organic vapor and acid gas cartridges and silver shield gloves during the task due to the potential exposure of TCE vapors in concentrations over the PPG STEL.

The following are included in the *Teslin* substrate department work exposure control program: TCE-specific hazard communication training (Appendix E); personal protective equipment (PPE) matrix (Appendix F); Barberton respiratory protection program (Appendix G); Job Safety

[27] In response to the EPA request for comment 12, 88 Fed. Reg. at 74776.

[28] This section responds to EPA's request for comment 46, 88 Fed. Reg. at 74777.

Analyses (JSA) with controls and assessed risks (Appendix H); and TCE alarm response procedures (Appendix I).

The building for the *Teslin* substrate operations is continuously monitored for indoor TCE concentrations. Samples are collected and analyzed from twelve (12) locations within the operations area. The results from the analyzers are fed into the *Teslin* substrate department integrated control software where the readings are routinely monitored. If these analyzers detect TCE levels above a predetermined direct reading level (20 ppm), an alarm will sound to alert the operators within the building and red lights located in the operations area will light. The TCE Alarm Response procedures (Appendix I) are in place providing guidance to employees on what actions to be taken. The procedures also provide the appropriate steps operators should take to identify the potential leak point and establish the requirement to barricade the affected area while the elevated TCE levels are present (in addition to wearing the required PPE, including respiratory protection). The system is set to alarm at 20 ppm in order to provide adequate notification before potentially exceeding the internal 25 ppm STEL.

D. TCE Exposure Controls in the PPG *Teslin* Substrate Department are Effective to Protect Workers, in Accordance with the Current PPG IPEL and OSHA PEL Using Traditional IH Strategy

1. Routine Task Exposure Potential and Control

PPG full shift TCE exposure monitoring results, performed over the last 5 years, have consistently been below the PPG IPEL of 5 ppm, TWA. In the past 5 years, statistical evaluation of exposure results in the *Teslin* substrate department indicate levels below 2.5 ppm with 95% confidence. Over the past 10 years, statistical evaluation of exposure results in the *Teslin* substrate department had levels below 6.8 ppm with 95% confidence over the past 10 years. This shows a progressive reduction in potential for workers' exposures over the past 5 years.

PPG short term TCE exposure monitoring results, performed over the last 5 years, have predominantly been below the PPG internal short term exposure limit (STEL) of 25 ppm. Due to variability of tasks and exposures monitored, statistical evaluation of these results indicates levels below 33.2 ppm with 95% confidence. Short term exposures are collected during tasks with higher potential for exposure, such as employees near open extractor/dryer doors and lids to perform activities such as changing rolls or cutting and rethreading *Teslin* substrate sheet. Because of the potential for exposure above the STEL, these tasks currently require a full-face respirator with a protection factor of 50, to adequately protect our employees to below our current internal STEL of 25 ppm, during these tasks.

2. Non-Routine Task Exposure Potential and Control

Non-routine tasks, for example, those that require operations or maintenance workers to open the doors and lids to the extractor/dryer area have the potential to expose workers above the STEL of 25 ppm for a period of time equal to or greater than 15 minutes, depending on the need. Therefore,

these tasks require respiratory protection as an interim protective measure, until engineering control solutions are developed and implemented to reduce exposure during these tasks further.

To PPG's knowledge, businesses with similar processes have not identified an engineering control solution to reduce exposures to these non-routine tasks to less than 25 ppm, or without need for respiratory protection. Moreover, there has never been either a governmental or recommended IH worker protection exposure limit as low as EPA's proposed ECELs. Sufficient time, therefore, is required to design effective solutions for exposure control during these non-routine tasks.

Eliminating the need for workers to enter the extractor/dryer area or finding a solution on how to maintain negative pressure and airflow away from worker breathing zones during these non-normal high risk exposure tasks, has not currently been defined by any similar process in other businesses that we have identified. Therefore, meeting the interim ECEL of 0.036 ppm, TWA and/or proposed ECELs of 0.0011 ppm or the alternative regulatory action of 0.0040 ppm, for the "highest" exposures, for non-normal operating conditions would not be possible, as far as we know.

Highest exposure tasks are at the greatest source of TCE, which is the extractor/dryer.[29] Any task that requires opening of the doors has the potential to increase exposure the most. Therefore, exposure controls will be prioritized on these tasks. However, during normal operating conditions, these doors remain closed, and negatively pressurized.

Using an IH 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 TCE. This is a pre-determined level, and out of the control of PPG. However, the exposure duration (minutes in a day) and frequency (days in a year) to known high exposure risk tasks at the extractor/dryer could be reduced by PPG, through considerations such as process control solutions, planned outages for preventative maintenance tasks requiring entry to these areas (replacing rolls, screws, etc.) and reducing the exposure time per task. These changes have the potential to reduce task frequency by 70-90% per year, per worker. Reducing the duration and frequency of these high-risk tasks per worker, as well as reducing the general production floor work area levels, would greatly reduce potential for worker exposure. Use of an American Industrial Hygiene Association (AIHA) qualitative industrial hygiene exposure tool indicated the potential to reduce the exposure from moderate-high to low-moderate exposure.

3. Spill Clean-Up

Another example of a non-routine task with the potential to exceed the PPG IPELs and require respiratory protection during the task is TCE liquid spill clean-up, leak, or rupture repair. It is not clear why EPA is proposing to conduct additional initial exposure monitoring (using personal breathing zone sampling) after the cleanup of a spill or repair of a leak, rupture or other breakdown. If this is for the purpose of deregulating an area so respirators no longer need to be used, this would be impractical with traditional IH sampling techniques, since receipt of results may take 1-2 weeks.

[29] This section is in response to comment 54, 88 Fed. Reg. at 74778.

If this is for the purpose of characterizing the exposure, it would not be representative of the task, after the task has been completed.

Direct reading of area TCE air monitoring should be able to be used to de-regulate the respirator required area, following a spill, leak, or release of TCE vapor requiring the establishment of the regulated area, and use of a respirator, versus use of full shift exposure monitoring, as indicated in the Proposed Rule.

E. The Current Proposed EPA Full Shift ECEL of 0.0040 ppm is Not Reasonable to Achieve

For PPG to reduce full shift worker exposures from 2.5 ppm with 95% confidence, to the proposed ECEL of 0.0040 ppm over an 8-hour TWA, all workers in the PPG *Teslin* substrate process areas would be required to wear PAPR respirators throughout the shift during normal, routine operating conditions. Workers performing non-routine (maintenance or upset operational condition) tasks that require opening of extractor/dryer doors and lid (which has an estimated exposure potential of 20-200 ppm), would require a SCBA or airline respirator with an assigned protection factor (APF) of 10,000 and evacuation of all workers not involved in the task from the production building during these tasks, and for some period of time, up to an hour or more, after. Alternatively, all workers in the *Teslin* substrate production areas would be required to wear SCBA or other NIOSH-certified supplied air respirator with an assigned protection factor (APF) of 10,000 on days that the non-routine tasks occur. It is an understatement to state that these scenarios would not be reasonable to enable operations to continue. They would not only be unreasonable, but they would render performing work impossible. Even if airline respirators could be used, they would cause tripping hazards, would prevent travel of mobile equipment, and would stop operations. SCBA respirators have a limited air supply (typically 30 minutes) and are not used or meant for long term work. Any use of a respirator throughout the day would reduce visibility and increase serious safety risks, including fatality potential, with mobile equipment in the area.

Respirators should not be required to be worn by employees throughout the day, during normal operations, as any respirator use 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. Respirator use should be limited to the duration of these high-risk exposure tasks and/or clean-up of spills. It is recommended that direct reading monitors be able to be used to verify reduction of exposure potential to an acceptable level following the high exposure tasks in work areas.

Use of an SCBA limited to workers performing these short duration, non-routine tasks may not be impossible, but are certainly unreasonable and would make the tasks more difficult, and potentially increase the task and exposure time, as well as create other safety risks. These risks could include ergonomic injury, potential for oxygen tank capacity to deplete prior to completion of the task, reduced worker satisfaction and well-being (impacting retention), visibility issues, potential pressure on the body systems – heart/lungs, not to mention resources to manage this equipment.

F. Obtaining Representative Full Shift Exposure Sampling Strategy, Respiratory Protection, and Feasibility of Controls Strategy

As stated previously, PPG has already obtained representative full shift exposure samples of employees in the *Teslin* substrate department. Any additional monitoring needed to obtain the required initial monitoring, updating the respiratory protection program as needed to comply, and establishment of an exposure control feasibility strategy will be able to be accomplished within 6 months after date of publication of the final rule in the Federal Register.

If exposure monitoring is to represent normal operating conditions, the timeframe of 6 months to collect initial monitoring is acceptable.[30] However, if exposure monitoring is to represent the "highest" exposures, during non-routine tasks, then more time is required since non-routine tasks are difficult to schedule, collect, and quantify consistently since they are variable, and dependent on the situation.

Instead of characterizing exposure based on the "highest" exposure measured, good industrial hygiene practice, with valid IH statistics, requires representative employee exposure samples obtained randomly, by collecting a sample so that there is equal probability of selecting any exposure period for any worker in a given similar exposure group (SEG) during the interval of the assessment. For instance, a random number generator may be used to select monitoring dates, work shifts, and individual workers. The IH sample collector notes conditions that can vary versus always representing the "highest" exposure values/tasks, which are not routine or representative of a typical workday. Then, statistics are employed to account for variability. A statistical 95%tile or upper confidence level is used to determine exposures that are out of compliance, or above the permissible occupational exposure limit, in lieu of the EPA proposed "highest" exposure measured.[31]

PPG currently uses direct reading area monitors to continuously monitor TCE throughout the manufacturing process area, carbon bed room, and ambient air. PPG is exploring upgrading monitoring technology to read a broader range of ppb and ppm values, and exploring the availability of personal monitoring devices with ability to average over a period of time, to better characterize work area direct readings and to estimate potential for exposure during normal and non-normal operations and maintenance tasks in order to prioritize and design effective exposure source control solutions over time.[32]

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[30] In response to EPA's request for comment 25, 88 Fed. Reg. at 74776.

[31] See, AIHA A Strategy for Assessing and Managing Occupational Exposures 4th Edition; *see also* ACC Comments.

[32] In response to EPA's request for comment 17, 88 Fed. Reg. at 74776.

IV. PPG Proposed Process and Engineering Control Approach to Reducing TCE Worker Exposure Over Time

PPG believes that using the current PPG IPEL of 5 ppm, over an 8-hour TWA and Action Level of 2.5 ppm is a reasonable starting point to use in the workplace chemical protection program (WCPP). As intentional work practices and engineering controls to reduce exposure are employed, there will be better information on what level is achievable.

PPG proposes a phased approach with an initial goal to continue to comply with the PPG IPEL of 5 ppm, over an 8-hour TWA and a STEL of 25 ppm, over a 15-minute period. This phased approach for reducing exposure over time would employ the hierarchy of controls pyramid strategy, to continue to seek substitute chemicals, design engineering control solutions, implement process improvements, strictly adhere to monitoring alarm procedures, JSAs, training, and PPE. An ECEL of 0.0040 ppm, however, is not possible to achieve or measure.

It is critical for *Teslin* substrate operation supervisors, operators, and maintenance to be involved in providing feedback and direction to PPG engineering and management on the design and implementation strategy of an effective exposure control plan and PPE program. They are knowledgeable about the opportunities for improvement and strategies that will be effective, and most importantly implemented consistently due to their involvement in designs that will be effective, functional, and facilitate production and work.

A. Exposure Control Strategy

Based on the statistical analysis of quantitative exposure assessments for normal operations over the past 5 and 10 years, as well as qualitative exposure assessments to evaluate effectiveness of controls for non-routine operations, PPG anticipates potential to reduce full shift exposure levels significantly. PPG does not anticipate that these potential changes will increase ambient exposure to TCE surrounding the *Teslin* substrate facility in Barberton, OH, because any additional ventilation exhaust from areas of airborne TCE will be exhausted through the carbon bed filters and evaluated for effectiveness through ambient air monitoring and filter changes.[33]

The use of TCE as a processing aid in the manufacture of polyethylene-silica lead acid battery separators by ENTEK and Microporous is similar to the process used by PPG to manufacture *Teslin* substrate. PPG continuously performs competitive technical benchmarking and even collaborates with other like-situated companies such as ENTEK and Microporous. Exposure mitigation measures could include activities such as the following, among others:

- Establish perimeters for high exposure tasks
- Improve TCE evacuation to the carbon bed, before opening equipment
- Add additional local ventilation
- Add lids in mixing area
- Reduce equipment opening by automating operational tasks

[33] *See* ACC Comments.

- Improve preventative maintenance to reduce emergency repairs requiring equipment opening
- Update monitoring and alarm response
- Add additional area and personal monitors
- Review carbon bed operating parameters to reduce emissions

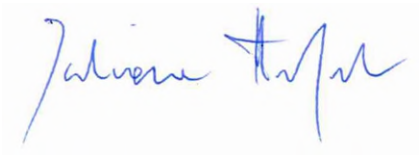
V. Conclusion

For the reasons articulated in these comments, including the accompanying appendices, PPG respectfully requests that EPA:

- Include in the final TCE risk management rule, the 6(g) exemption for the manufacturing of specialty polymeric microporous sheet materials (*Teslin* substrate), as described in PPG's TSCA Section 6(g) Exemption Request, June 29, 2023, and without restricting any applications of *Teslin* substrate.
- Withdraw both proposed ECELs, because as described in detail in Appendices A, B and C, neither ECEL reflects either the best available science or the weight of the scientific evidence, as required under TSCA section 26.
- Withdraw the proposed ban on disposal of TCE in wastewater because EPA has failed to justify such a blanket prohibition.

PPG sincerely appreciates the Agency's consideration of these comments. Please contact me should you have any questions regarding this submission.

Sincerely,



Juliane Hefel
Vice President
Specialty Coatings & Materials

Attachments: Appendices A-I