BUILD ELECTRONICS BETTER

U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics 1200 Pennsylvania Ave NW Washington, DC 20460-0001	Docket Number EPA-HQ-OPPT-2023-0613 via Federal eRulemaking Portal: http://www.regulations.gov Comments submitted 14 May 2024

IPC is a non-profit, member-driven organization and the leading source for industry standards, training, industry intelligence, and public policy advocacy for the global electronics industry. IPC serves more than 3,200 member-companies around the world in every segment of the electronics manufacturing industry including design, printed circuit board manufacturing, electronics assembly, test and advanced packaging, suppliers, and original equipment manufacturers. In the United States, IPC membership includes more than 1,400 companies across this diverse collection of industries that are integral parts of the economy.

On November 18, 2019, IPC met with the U.S. Environmental Protection Agency (EPA) to review the electroless copper plating condition of use (COU) for formaldehyde.[1] On June 8, 2020, IPC submitted public comments on EPA's *Draft Scope of the Risk Evaluation for Formaldehyde* to correct information EPA had misclassified/misidentified from the November 18, 2019, meeting.[2] IPC is pleased to provide comments on EPA's draft risk evaluation for formaldehyde. IPC's comments are focused on the use of formaldehyde as an essential reducing agent in electroless copper formation. IPC disagrees with EPA's identification of unreasonable risks to workers from this COU. Below we have highlighted specific deficiencies with EPA's draft risk evaluation.

We begin by discussing EPA's evaluation of occupational monitoring data. Then, we discuss EPA's dermal exposure modeling estimates that we believe were focused on identifying unreasonable risks rather than objectively evaluating the presence and/or absence of unreasonable risks. We conclude our comments with a discussion of EPA's hazard values and our concerns with the quality and reliability of EPA's documentation of this information.

Occupational Monitoring Data

IPC has concerns with EPA's evaluation of the monitoring data. As an example, we discuss the data EPA summarized under the Processing Aid COU (*i.e.*, oxidizing/reducing agent). EPA stated under Table 4-33 of the *Draft Occupational Exposure Assessment for Formaldehyde* that the area monitoring data consisted of two samples, referencing Ho *et*

1 EPA (2019), *Meeting with IPC and EPA to Discuss Conditions of Use for Formaldehyde*, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2018-0438-0025/content.pdf.

2 IPC (2020), *Public Comments Submitted on June 8, 2020*, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2018-0438-0050/attachment_1.pdf.

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al. (2013).[3] EPA used the area monitoring data as short-term exposure estimates and listed the values as 0.019 ppm and 0.023 ppm.[4] IPC compared these values with the values listed in EPA's *Formaldehyde Draft RE Occupational Monitoring Data Summary*.[5] Under the "Processing Aid" tab, EPA stated that the number of data points was six for two different sites and listed "Discrete value[s]" of 0.016 ppm and 0.0229 ppm and "FA Short-term TWA [time-weighted average] Concentration[s]" of 0.016 ppm and 0.023 ppm. EPA stated that the data location for these values was from "PDF pg 4 & 7 (Tables 1 and 3)" of Ho *et al*. (2013).

Ho *et al*. (2013) visited two electroplating factories in summer (June 2011-August 2011) and winter (December 2011-February 2012) and collected six samples during each visit (*i.e.*, 12 total samples).[6] Under Table 3, the authors reported mean values of 0.0136 ppm for Factory A and 0.0187 ppm for Factory B.[7] Under Table 4, the authors used the reported mean values for quantifying risks. The reported mean values under Table 4 were, however, 0.0167 ppm for Factory A and 0.0229 ppm for Factory B.[8] The discrepancy in these tables is unclear. Ho *et al*. (2013) did not provide the individual sample values. EPA determined, however, that the overall data quality for Ho *et al*. (2013) was "Medium."[9] EPA's data quality evaluation of Ho *et al*. (2013) included a comment under the reliability domain, which stated "Assessment uses high quality data that are not from frequently-used sources and ***there are no known quality issues***. [emphasis added]"[10] The discrepancies in Ho *et al*. (2013) and in EPA's documents for this one study are concerning and suggest issues with the quality and reliability of EPA's review of the monitoring data in general.

EPA stated under the Processing Aid COU that "It should be noted that 7 percent of the 8-hour TWA PBZ, 66 percent of the 15-minute TWA and one of the short-term samples measured below the LOD." EPA went on to state that "To estimate exposure concentrations for this data, EPA followed the *Guidelines for Statistical Analysis of Occupational Exposure Data* [the "1994 Guidelines"][citation omitted], as discussed in

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3 EPA (2024a), *Draft Occupational Exposure Assessment for Formaldehyde CASRN 50-00-0*, at 90, available at https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-occupational-exposure-assessment-for-formaldehyde-public-release-hero-march2024.pdf.

4 *Id*. at 91.

5 EPA (2024b), *17. Draft RE Occupational Monitoring Data Summary*, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2023-0613-0026/content.xlsx.

6 Ho *et al*. (2013), *Hazardous Airborne Carbonyls Emissions in Industrial Workplaces in China*, JOURNAL OF THE AIR & WASTE MANAGEMENT ASSOCIATION, 63, at 865, available at https://doi.org/10.1080/10962247.2013.797519.

7 *Id*. at 869.

8 *Id*. at 875.

9 EPA (2024a), *supra* note 3, at 90.

10 EPA (2024c), *Systematic Review Supplemental File: Data Quality Evaluation and Data Extraction Information for Environmental Release and Occupational Exposure*, Draft Risk Evaluation for Formaldehyde, at 1512, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2023-0613-0039/content.pdf.

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Section 2.5.1."[11] EPA summarized its use of the 1994 Guidelines under Section 2.5.1. as follows:[12]

> For datasets including exposure data that were reported as below the limit of detection (LOD), EPA estimated the exposure concentrations for these data, following EPA's *Guidelines for Statistical Analysis of Occupational Exposure Data* [citation omitted]. That report recommends using the $LOD/\sqrt{2}$ if the geometric standard deviation of the data is less than 3.0 and $LOD/2$ if the geometric standard deviation is 3.0 or greater.

IPC reviewed the 1994 Guidelines and confirmed the information EPA provided. IPC notes, however, that EPA's summary was not complete. The 1994 Guidelines also state the following:[13]

> If 50% or more of the monitoring data are nondetectable, substitution of any value for these data will result in biased estimates of the geometric mean and the geometric standard deviation [citation omitted]. If it is necessary to calculate statistics using data sets with such a large proportion of nondetectable data, the potential biases introduced by these calculations should be described when presenting the results of the analyses.

EPA did not, however, discuss the potential biases for the 15-minute samples. EPA merely stated that "There is some uncertainty in the 15-min estimates since over 50 percent of the samples were below the LOD."[14] IPC encourages EPA to revise its discussion of these samples and to characterize the potential biases that these samples may have introduced to EPA's findings of unreasonable risk. IPC notes, however, that the data EPA summarized for the Processing Aid COU warrant consideration in the context of industry compliance with the U.S. Occupational Safety and Health Administration's (OSHA) occupational exposure limits.[15] As shown in Table 1, the central tendency and high-end 8-hour exposures represent 5% and 33% of the allowable OSHA permissible exposure limit (PEL), respectively. The 15-minute and short-term exposure levels were only 1-9% of the allowable OSHA short-term exposure limit (STEL). Further, the central

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11 EPA (2024a), *supra* note 3, at 91.
12 *Id*. at 29.
13 EPA (1994), *Guidelines for Statistical Analysis of Occupational Exposure Data: Final*, at 48, available at https://nepis.epa.gov/Exe/ZyPDF.cgi/9100CHBH.PDF?Dockey=9100CHBH.PDF.
14 EPA (2024a), *supra* note 3, at 91.
15 29 CFR 1910.1048, available at https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1048.

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tendency exposures and high-end exposures were less than 10% or less than 50% of the OSHA action level, respectively.

Table 1. EPA's Processing Aid Exposure Data versus OSHA's Exposure Limits

EPA Data			**% of OSHA Limits**		
Exposure Concentration Type	Worker Exposures		OSHA 8-hr PEL, STEL, and Action Levels	Worker Exposures	
	Central Tendency (ppm)	High End (ppm)		Central Tendency (ppm)	High End (ppm)
8-hour TWA	0.04	0.25	0.75	5%	33%
Action Level	0.04	0.25	0.5	8%	50%
15-min TWA	0.07	0.18	2	4%	9%
Short-Term TWA	0.019	0.023	2	1%	1%

Dermal Exposure Modeling

EPA stated that "Formaldehyde dermal exposure data were not reasonably available for any of the COUs considered in [its] assessment."[16] EPA therefore used a modified version of the *EPA Dermal Exposure to Volatile Liquids Model*. IPC has concerns with the inputs EPA used in this model. For example, one of the input parameters is "the quantity [of the chemical substance] remaining on the skin after an exposure event," identified as "*Qu*."[17] EPA used values for *Qu* of 2.1 mg/cm^2-event for routine, high-end exposures and 1.4 mg/cm^2-event for central-tendency exposures.[18]

For spray applications, EPA used values for *Qu* of 10.3 mg/cm^2-event for high-end exposures and 3.8 mg/cm^2-event for central-tendency exposures.[19] The *Qu* values were based on experiments EPA performed in the early 1990s using highly viscous liquids (*e.g.*, mineral oil, cooking oil, and bath oil).[20] EPA initially intended to use six liquids, but it had to omit three of the liquids (*i.e.*, 50:50 water:water-soluble oil; water; and 50:50 water:ethanol) "because an acceptable experimental procedure to address volatilization/evaporation losses could not be developed for them."[21] IPC questions EPA's use of highly viscous liquids to inform *Qu,* given that formaldehyde exists as a gas at

16 EPA (2024a), *supra* note 3, at 33.
17 *Id*.
18 *Id*.
19 *Id*. at 34.
20 See, generally EPA (1992), *A Laboratory Method to Determine the Retention of Liquids on the Surface of Hands*, EPA 747-R-92-003, available at https://hero.epa.gov/hero/index.cfm/reference/download/reference_id/1064974.
21 *Id*. at 8.

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room temperature and as a low-viscosity liquid when in solution (*e.g.*, formaldehyde/methanol solutions).

Hazard Values

IPC has one specific concern with EPA's hazard values. Under Table 3-1 of the *Draft Human Health Risk Assessment for Formaldehyde*, EPA listed the hazard value for "Inhalation Chronic non-cancer (Long-term, >6 months)" as "$BMCL_{10}$ = 0.017 ppm (0.021 mg/m^3)".[22] This value was, however, listed as 0.017 ppm and 0.21 mg/m^3 under the "Hazard Values" tab in EPA's *Formaldehyde Draft RE Occupational Risk Calculator*.[23] It does not appear that EPA used the "mg/m^3" values for quantifying risks, given that the exposure estimates were presented as "ppm" values.[24] We mention this error, however, because it is another representative example that raises questions about the quality and reliability of EPA's review of the information used in its draft risk evaluation.

Concluding Remarks

IPC is committed to working with its relevant member companies to ensure the continued safe use of formaldehyde. We do not, however, believe that EPA's determination of unreasonable risks to workers that use formaldehyde as an essential reducing agent in electroless copper formation is reflective of real-world conditions. EPA appears to have rushed to complete the draft risk evaluation for formaldehyde at the expense of ensuring the quality, reliability, and integrity of the information used to inform its determinations in that document. IPC appreciates the opportunity to comment on EPA's draft risk evaluation for formaldehyde. We are, however, concerned that EPA only gave members of the public 60 days to comment on a document that is collectively thousands of pages long.

The point of contact for these comments is Kelly Scanlon, DrPH, CIH, Lead Sustainability Strategist at IPC (kellyscanlon@ipc.org, 202-661-8091).

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22 EPA (2024d), *Draft Human Health Risk Assessment for Formaldehyde CASRN 50-00-0*, at 74, available at https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-human-health-risk-assessment-public-release-hero-march-2024.pdf.

23 EPA (2024e), *15. Formaldehyde Draft RE Occupational Risk Calculator*, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2023-0613-0024/content.xlsx.

24 EPA (2024a), *supra* note 3.

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