

Request for Correction
by the
Semiconductor Industry Association (SIA)
On the
Toxic Substances Control Act (TSCA) Risk Evaluation for
N-Methylpyrrolidone (NMP)

85 Fed. Reg. 86558 (Dec. 30, 2020)

[EPA–HQ–OPPT–2019–0236; FRL–10017–18]

Submitted June 3, 2021

The Semiconductor Industry Association (SIA),¹ representing 98 percent of the semiconductor industry in the U.S., submits this request for the correction of information (“Request for Correction”) related to the final risk evaluation for N-Methylpyrrolidone (NMP) issued by the Environmental Protection Agency (“EPA”).² This request is submitted under the Information Quality Act (“IQA”)³ and the implementing guidelines issued, respectively, by the Office of Management and Budget (“OMB”)⁴ and EPA.⁵

Background

EPA undertook and completed a Risk Evaluation for NMP in the context of Section 6 of TSCA. Section 26 of the amended statute requires that such evaluations consider all information reasonably available to the Agency, meet the scientific standards in law for use of the best available science, and the application by EPA assessors (and peer reviewers) of a weight-of-scientific-evidence approach when conducting risk evaluations.⁶ EPA has pledged that the application of these standards will be documented throughout the risk evaluation process and available for public comment.⁷

EPA is required by law to rely on the risk evaluation when drafting a proposed regulation under Section 6 of TSCA to mitigate such risks. Accordingly, the risk evaluation must be recognized

¹ SIA is the trade association representing U.S. companies engaged in the research, design and manufacture of semiconductors. Semiconductors are the fundamental enabling technology of modern electronics that has transformed virtually all aspects of our economy, ranging from information technology, telecommunications, and health care, to transportation, energy, and national defense. The U.S. is the global leader in the semiconductor industry, and continued U.S. leadership in semiconductor technology is essential to America’s global economic leadership. More information about SIA and the semiconductor industry is available at www.semiconductors.org.

² The final risk evaluation is available at https://www.epa.gov/sites/production/files/2020-12/documents/1_risk_evaluation_for_n-methylpyrrolidone_nmp_casrn_872-50-4.pdf.

³ Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, P.L. 106-554; 44 U.S.C. § 3516 (notes).

⁴ 67 Fed. Reg. 8452 (Feb. 22, 2002) (“OMB Guidelines”).

⁵ EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency, EPA/260R-02-008 (October 2002) (“EPA Guidelines”).

⁶ The 2016 amendments to TSCA in no way superseded the more general obligations the Agency has pursuant to the IQA; if anything, TSCA Section 26 served to further “raises the bar” for EPA when undertaking science-based risk evaluations and making risk-management determinations pursuant to TSCA. Many of the terms Congress added to Section 26 of TSCA in its 2016, are echo-ed in the Agency’s IQA Guidelines.

⁷ <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca>.

under the standards of the IQA and EPA's Guidelines, as an "influential" document that by necessity will have a "clear and substantial impact" on private sector decisions such as efforts of processors, users, consumers, and retailers to "deselect" use of substances EPA identifies as of concern, and to have a "clear and substantial impact" on the related community when the Agency's findings become the driver for restrictions in a Section 6 regulation under TSCA. Thus, it is imperative that any scientific errors and omissions in a final risk evaluation be timely addressed and corrected, and, therefore, we ask EPA to consider this request for correction and undertake the necessary corrections swiftly.

Basis for Request and Need for Correction

EPA concluded in the final evaluation that certain conditions of use of NMP in the semiconductor industry present an "unreasonable risk" to semiconductor workers. SIA requests that EPA correct this erroneous conclusion. We believe this conclusion is erroneous for two fundamental reasons:

1. EPA did not use the high-quality data and information provided by the SIA; and
2. EPA assumptions about surface area and duration of exposure are incorrect and do not occur in the semiconductor industry.

If EPA relied on the more accurate information provided by SIA concerning the actual conditions of use and exposure in the industry (rather than adopting the estimates and modeling approach used by EPA) and met the scientific standards in the pertinent statute, EPA would have properly concluded the use of NMP in the semiconductor industry does not present any unreasonable risks to semiconductor workers.

The attached report⁸ sets forth the technical errors reflected in the EPA risk evaluation with a focus solely on EPA's assessment of the use of NMP in the semiconductor industry. The key points warranting a timely correction by EPA are set forth below.

A. SIA Provided Data and Information in the Record EPA Deemed to be "High Quality"

SIA submitted voluminous data and information to EPA throughout the risk evaluation process, documenting in detail the conditions of use of NMP in the semiconductor industry. Among other things, SIA provided EPA with the following:

⁸ Cardno ChemRisk, May 24, 2021. Review of the TSCA Section 6 Risk Evaluation of the Conditions of Use of NMP in the Semiconductor Industry.

- Several sets of detailed comments to EPA describing industry practices, including air monitoring data, photos of workers in PPE, documents concerning employee training, engineering controls, and workplace practices, and other information;⁹
- Data and results of extensive air monitoring at semiconductor fabs;¹⁰
- A meeting with EPA officials in November 2017 to summarize the conditions of use of NMP at semiconductor fabs and to respond to any request for information; and.
- Hosted a group of EPA officials, including some engaged in NMP's risk evaluation, to tour a semiconductor fab of a member company in February 2019 to provide a first-hand understanding of the use and handling of chemicals in a fab.

The information provided by SIA included detailed information on worker exposure to NMP at semiconductor fabs. The information included documentation of the use of personal protective equipment (PPE), the duration of work tasks, and the duration and extent of dermal exposure to NMP, air monitoring data, and other supporting information. The industrial hygiene air exposure monitoring sampling data indicates the extremely low potential exposure to NMP when used in fab operations which take place in a controlled environment inside manufacturing equipment¹¹ and at other points in a fab facility where human contact may occur.

Importantly, EPA characterized the information on conditions of use submitted by SIA as "high quality" (EPA, 2020).¹²

⁹ SIA submitted information to EPA at various stages in the NMP Risk Evaluation and rulemaking processes, including: [

- a. SIA Comments On the Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: N-Methylpyrrolidone (NMP) (EPA-HQ-OPPT-2016-0743) (Submitted March 15, 2017).
- b. SIA Comments on EPA Proposal on Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464 (Jan. 19, 2017) (EPA Docket # EPA-HQ-OPPT-2016-0231) (Submitted May 19, 2017).
- c. SIA Comments on Problem Formulation of the Risk Evaluation for N-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) CASRN: 872-50-4 (EPA-HQ-OPPT-2016-0743) (July 16, 2018).

¹⁰ SIA N-Methylpyrrolidone Risk Management Measures and Worker Exposure Monitoring Results (February 22, 2019). We also provided the Agency with data from monitoring at fabs in Europe, which we determined were accurate and representative of the exposure rates likely to be found at semiconductor fabs in the United States. SIA Comments To the EPA Docket on Methylene Chloride and N-Methylpyrrolidone (NMP) (EPA Docket # EPA-HQ-OPPT-2016-0743) (Submitted September 18, 2017).

¹¹ Semiconductor manufacturing equipment – enclosed, interlocked, ventilated, and automated manufacturing equipment (tools) which separate employees from the product wafer and process chemicals. Contemporary tools are designed and fabricated to meet the requirements of SEMI S2 – *Environmental, Health, and Safety Guideline for Semiconductor Manufacturing Equipment 11* and SEMI S6 – *Environmental, Health, and Safety Guideline for Exhaust Ventilation of Semiconductor Manufacturing Equipment*. The SEMI guidelines include provisions that ensure hazardous gases, fumes and vapors are controlled such that work place concentrations are less than 1% of the American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit value (TLV) or permissible exposure limit (PEL) during normal equipment operation. SEMI S2 requires emissions not exceed 25% of the TLV or PEL in the anticipated worst-case breathing zone during equipment failures and maintenance activities.

¹² After EPA issued its draft risk evaluation relying on these erroneous assumptions, SIA highlighted EPA's failure to consider realistic conditions of use to EPA's Science Advisory Committee on Chemicals (SACC). See Comments of the Semiconductor Industry Association (SIA) To the Science Advisory Committee on Chemicals (SACC) On the Draft Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone (NMP), 84 Fed. Reg. 60,087 (Nov. 7, 2019), [EPA-HQ-OPPT-2019-0236; FRL-10001-87], Submitted November 26, 2019. The SACC reviewed the record and called on EPA to address these concerns.

B. EPA Relied on Incorrect Assumptions on Conditions of Use

Despite the extensive information and data in the record, EPA ignored or discounted this information and instead used assumptions and estimates on conditions of use not found in the industry. As a result of this deficiency, EPA has failed to meet its obligations under Section 26 of the amended statute to consider information that is readily available and apply a weight-of-the-evidence approach when assessing risks.

The primary errors committed by EPA were its incorrect assumptions about the (1) skin surface area exposed to liquid NMP and (2) dermal contact time.

(1) Skin surface area exposed to NMP

EPA relied on inaccurate and hypothetical assumptions about the skin surface area exposed to liquid NMP. EPA failed to take into account standard industry industrial hygiene practices, such as the use of gloves and other PPE. Under standard industry practices, there is minimal risk to semiconductor workers of exposure to NMP.

The NMP risk evaluation failed to incorporate standard workplace practices specifically required in the semiconductor industry, including information on worker training and PPE provided in SIA's submission and presentations made to EPA's peer review panel. Instead, the Agency relied on hypothetical assumptions about the skin surface area exposed to liquid NMP. These assumptions are unrealistic and unfounded based on the data provided by SIA; more significantly, assumptions and estimates should be accorded lesser weight when a weight-of-the-evidence approach is being applied.

(2) Dermal contact time

EPA overestimated the duration of liquid contact by assuming exposure conditions that are equivalent to immersion in NMP for up to 12 hours. This assumption does not incorporate the work tasks described by SIA and documented in the data and information included in the risk evaluation record. In fact, the work tasks at a semiconductor fab result in very limited opportunities for contact. Further, this assumption neglects industry standards for good IH practices which require the removal and disposal of potentially-contaminated gloves. The final evaluation also fails to acknowledge that NMP will evaporate from the skin or glove surface area over time. Evaporation is an important consideration when assessing the dermal exposure potential of volatile or semi-volatile chemicals.

Conclusion

Under TSCA, EPA is required to evaluate chemical substances under their "conditions of use," which are defined as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of."¹³

The industry provided high quality data on conditions of use, risk management measures, and employee exposure monitoring that demonstrates a high level of worker protection. If EPA had used proper assumptions on the actual conditions of use as reflected in the information SIA supplied for the risk evaluation record and conducted modeling for all pertinent scenarios based on these real-life conditions, EPA would have concluded there were no unreasonable risks to

¹³ 15 U.S.C. §2602(4).

workers in the semiconductor industry from the use of NMP. By relying on flawed assumptions regarding conditions of use, however, EPA reached erroneous margins of exposure (MOE) for workers in the industry. Instead, EPA Reached its Conclusion of an “Unreasonable Risk” to semiconductor workers based on assumptions and estimates of conditions of use not found in the semiconductor industry in the U.S.

Action Requested

SIA requests that EPA correct the final Risk Evaluation for NMP to remove scenarios in the “PBPK” model analyses for workers in the semiconductor industry that never occur in this industry. We request that EPA adopt the recommendations provided by SIA based on the industry’s data and information pertinent to the actual conditions of use in that sector. These attributes include the replacement of estimates and assumptions made as proxies for the recommendations provided by EPA for dermal exposure contract times, shift durations, and the extent (surface area) of skin contacted. SIA would be glad to provide further details to EPA assessors to ensure there is a clear understanding of how the data and information SIA provided previously credibly and reasonably align with the recommendations SIA provided.

SIA considers prompt action on this Request for Correction to be both appropriate and necessary in order for the Agency’s final Risk Evaluation to be corrected in accordance with the purpose and statutory intent of the IQA and 2016 amendments to TSCA, and to enable EPA to consider the corrections in the course of drafting TSCA Section 6 risk management regulations for NMP the Agency must propose before the end of the year.

For these reasons, SIA respectfully requests that, when the Final Risk Evaluation is corrected as discussed above, EPA clarify that the revisions supersede the original document’s erroneous conclusions on the use of NMP in semiconductor manufacturing and that the revised Evaluation appropriately concludes these conditions of use do not present an “unreasonable risk” to semiconductor workers.