SEMICONDUCTOR INDUSTRY ASSOCIATION

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 Semiconductor Industry Association (SIA)[1] appreciates the opportunity to submit the following comments to the Science Advisory Committee on Chemicals (SACC) of the U.S. Environmental Protection Agency (EPA) on the Draft Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone (NMP).

## Introduction

To better inform the Agency's Risk Evaluation for NMP, SIA has provided information and data to EPA in several forms. Those data and information are attached to this submission for ease of reference. The prior submissions include SIA's 2019 workplace exposure study in which air sampling data and the use of inhalation and dermal personal protective equipment (PPE) were detailed. In addition, in March 2017, SIA provided written comments on EPA's Preliminary Use Assessment for NMP, and SIA provided briefings during November 2017 and again in April 2018 describing the workplace exposure controls in its members semiconductor fabrication facilities (fabs) that ensure exposures to NMP are minimized by the use of engineering controls and PPE. Finally, SIA arranged for a fab site visit so Agency risk assessors could observe directly the operations at a semiconductor manufacturing fab and better understand how human exposures to chemical substances, including NMP, are nearly eliminated in semiconductor production operations. Such information and data clarify that semiconductor manufacturing is a unique process undertaken in near-pristine conditions where no unreasonable risks to workers attributable to NMP exposures are expected to occur.

[1] SIA is the trade association representing leading U.S. companies engaged in the 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, health care, 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 continued global economic leadership. More information about SIA and the semiconductor industry is available at www.semiconductors.org.

SIA requests the SACC to examine carefully the entirety of this information. In light of the overwhelming strength of this information and data, SIA requests the SACC reassess the Agency's draft findings with respect to EPA's estimates of human exposures that occur under the conditions of use present in semiconductor fabs. Taking into account the information available to the Agency and applying a weight-of-the-evidence standard, SIA requests the SACC to recommend that the Agency use exposure estimates that are more fit-to-purpose for assessing potential risks of exposures to NMP that might occur in semiconductor fab facilities. Operations that occur in fabs are unique and the workplace practices are, by definition, exposure limiting to ensure the cleanliness of the fab and to eliminate opportunities for contamination of semiconductor wafers throughout all process steps.[2] SACC should advise EPA that the data available to EPA are sufficient for the conditions of use in semiconductor fabs to be considered separately from the other categories of use EPA has aggregated for purposes of the draft Risk Evaluation. Accordingly, EPA should be encouraged to reconsider the conditions of use for the semiconductor industry and to take into account:

1. the duration and frequency of tasks during which exposures to NMP can occur (e.g., truck unloading),
2. the personal protective equipment (PPE) that is used during such operations,
3. the engineering controls that are employed to minimize exposure, and
4. the sampling data indicates the extremely low potential exposure to NMP when used in fab operations which take place in in a controlled environment inside manufacturing equipment and in maintenance tasks.

**Discussion**

In concluding that the use of NMP in semiconductor manufacturing posed an unreasonable risk of injury to worker health, EPA made several significant errors and relied on inaccurate assumptions, including the faulty assumption that the conditions of use in semiconductor operations could be evaluated within the same category as other industry sectors. In doing so, EPA failed to rely on the best available information and did not apply a weight-of-the evidence approach. The following summarizes the Risk Evaluation's more troublesome deficiencies:

1. <u>EPA mischaracterized the semiconductor industry's use of NMP, which has led to multiple substantive errors in its risk determination</u>. SIA submitted contemporary information (see SIA's 2019 workplace exposure study at Appendix A) on worker exposure at semiconductor fabs collected by member companies.[3] These data included air sampling data and details regarding the durations and frequencies of tasks undertaken by workers in fab facilities. The

[2] As addressed in the 2019 study SIA provided, there are certain support functions that occur beyond the clean-room environment of the fab that nevertheless are carried out in controlled and monitored conditions that require the use of appropriate PPE and in spaces that generally include the use of engineering controls to limit exposure to chemicals of potential concern.
[3] This study was determined to be of high quality by EPA assessors.

SIA submissions (Appendix A and in presentations made to EPA in Appendix B) also described the risk management measures implemented at fab facilities including depictions and descriptions of PPE worn by workers to minimize the potential that they might come in contact with NMP as well as information concerning the structure and operations of fab facilities which are designed to largely eliminate opportunities for any human contact with wafers and the chemicals used within semiconductor manufacturing equipment.[4] These data and the additional information SIA provided (e.g., SIA's March 2017 comments at Appendix C) clearly demonstrated that fab workers have minimal opportunities for direct exposures to NMP and use PPE and engineering controls that reduce exposures to levels which present no unreasonable risks to human health. For example:

- Only 5 of the 118 personal air samples that SIA member companies collected showed concentrations of NMP above the limits of detection. Three of the five samples (0.01, 0.02, and 0.07 ppm) were for fab maintenance tasks. Two of the five were for waste truck load / virgin NMP truck offload - tasks that occur at many industrial sites and that are not specific to semiconductor manufacturing where LOD ranged between 0.011 ppm and 1.18 ppm.
- Of the 5 measured samples that did have NMP concentrations above LOD, the highest 8 hr. TWA concentration was 1.18 ppm for tanker truck offloading. The virgin NMP truck offload task is conducted once per year and corrective actions have been identified to reduce potential exposures. The measured exposure in this instance was only 0.18 ppm above the CAL OSHA 1.0 ppm 8 hr. TWA, more than an order of magnitude lower than the 3.5 ppm ECHA limit and is 10 times lower than the AIHA's 10 ppm 8 hr. WEEL.
- SIA submitted details on the tasks durations and frequencies which showed task durations are short and human exposures are accordingly time-limited. EPA apparently did not use these data; instead, EPA's draft Risk Evaluation erroneously assumed workers could be exposed at such levels throughout their entire work shift (8-12 hours), rather than episodically.
- EPA Table 4-49 indicates that EPA made the assumption that semiconductor workers have direct dermal contact with liquid NMP and/or liquid mixtures of NMP. This assumption is entirely incorrect. SIA has described its engineering controls and chemical handling procedures to EPA in presentations and in

[4] 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.

written documentation that has been submitted to EPA (see Appendices A-C). These procedures are designed explicitly to prevent any dermal contact with liquid NMP or other potential forms of residual NMP.

- The Agency's application of a safety factor of 10 to the skin surface area because "workers … are likely to wear gloves" and employees are likely to "have at least basic training on glove usage" is still mischaracterizing the industry's use of NMP. Skin surface area available for direct liquid dermal contact by fab workers should be considered zero for the purpose of this Risk Evaluation. The semiconductor industry uses specific procedures for selecting the proper gloves for the particular chemical and task. These procedures are documented, and cover both the selection of the glove, and the procedure for donning and removing the glove (see example training in Appendix D). In recognition of these procedures, the glove protection factor should be at least, if not greater than, 20, and certainly not 10.
- SIA provided information on the extensive risk management measures and engineering controls employed in the semiconductor industry, including personal protective equipment (PPE). When modeling potential skin exposure, EPA did not reference the use of chemically resistant gloves such as the MAPA Trionic gloves[5] (Appendix E) which are commonly used in the industry. Instead, the draft Risk Evaluation suggests EPA assumed that as much as one full hand or perhaps two hands are directly exposed. This is an incorrect assumption for this industry, is inconsistent with information SIA has provided to EPA, and does not reflect a weight-of-the-evidence approach.
- The basis for the Agency's handling of air sampling data with observations falling below detection limits is not transparent in the draft Risk Evaluation. Most of the data submitted by SIA reflected readings that were below detection limits and below the lowest US based occupational exposure limit, e.g., CAL OSHA PEL. The draft Risk Evaluation does not explain how non-detect data could lead to a preliminary conclusion that an 'unreasonable risk of injury to worker health' exists in semiconductor fab operations. SIA requests that the SACC should require EPA to fully explain and justify its assumptions and provide a record of the values EPA used for the limit of detection (LOD) in the Agency's statistical adjustments. The SIA requests that the SACC review the validity of EPA's adjustment methods in light of the SIA's study – which the Agency itself determined to be of high quality. Specifically, the SACC reviewers should consider the appropriateness of such methods and the conclusions EPA's draft Risk Evaluation has drawn for adjusting the data when a reliable study documented that 96% of measured values in fab and support operations fell below the LOD and well below the lowest US based occupational exposure limit (CAL OSHA PEL). Such methods discourage affected industries from gathering and submitting contemporary data and undermine EPA's stated commitment to use a weight-of-the-evidence approach.

[5] Breakthrough time for N-methyl-2-Pyrrolidone 99% using MAPA Trionic gloves http://www.mapa-pro.com/our-gloves/protections/critical-environments/p/g/trionic-e-194.html#chemical_chart.

- NMP Concentrations in specific conditions of use should be considered. SIA provided data on NMP weight percentage in chemical formulations and waste as part of its 2019 study; this data should be used in the Agency's PBPK modeling and overall draft Risk Evaluation.

2. EPA's approach and assumptions lack transparency. On the basis of the draft Risk Evaluation and the materials made public in the supplemental assessments, SIA reviewers have not been able to reproduce EPA's statistical analysis when interpreting the air sampling results. Very limited details of the PBPK model and its inputs are provided in the draft Risk Evaluation; thus, there is a lack of transparency regarding how worker blood concentrations were estimated. This lack of transparency makes it difficult for other scientists to fully assess whether EPA is making use of the best available science.

   The SACC should challenge EPA to immediately make public the full details of its PBPK model for NMP for use by interested and affected parties. This information should include the PBPK code used for this assessment, model input parameters, and tabular outputs. SIA further requests the SACC review EPA's modeling to ascertain if EPA made appropriate use of the data SIA submitted and properly interpreted the information on conditions of use that were provided by the semiconductor industry.

3. EPA used a PBPK model software that is no longer commercially available and also used incorrect model inputs.
   - For purposes of the 2019 draft Risk Evaluation, EPA used the Acs1X code package for PBPK modeling. Acs1X was sunset in November 2015, is no longer supported by its developer, and the program is not commercially available[6]. EPA's use of this model software makes it extremely challenging to replicate and validate the Agency's results, and makes it difficult to determine if the best available scientific methods were brought to bear.

4. It is inappropriate and unnecessary to group the semiconductor industry's conditions of use of NMP with other industrial sectors. EPA has available the information needed to better understand and reasonably evaluate the potential for semiconductor workers to be exposed to NMP under the conditions of use unique to semiconductor fabrication facilities. Such information represents the best information available for such conditions of use and consequently should be weighted heavily when applying a weight-of-the-evidence approach. Nevertheless, EPA's draft Risk Evaluation illogically grouped semiconductor manufacturing along with other industrial activities despite the considerable data and information SIA provided to the Agency. For instance, semiconductor manufacturing was grouped with "Paint additives and coating additives not described by other codes" (p.315) and "Solvents (for cleaning or degreasing): Use in electrical equipment, appliance and component manufacturing" (p.316-

[6] Toxicol Sci. 2017 Jul 1;158(1):23-35. doi: 10.1093/toxsci/kfx070.

317). EPA's assumption that the practices in the semiconductor manufacturing industry are representative of other electronics manufacturing operations also is not accurate. Semiconductor manufacturing involves the fabrication of circuits that are typically less than 100 nanometers in dimension and requires exceptionally precise and controlled manufacturing equipment and processes. Such processes occur within equipment which are, by design, intended to isolate the manufacturing process and chemicals from workers.

SACC should recognize readily and then advise EPA that it would greatly reduce scientific uncertainty and enhance the Agency's ability to apply a weight-of-the-evidence approach if EPA would evaluate the semiconductor sector as a stand-alone condition of use for NMP rather than as part of these broader sectors.

5. The SIA and its members intend to review the draft risk assessment and supplements in greater detail. A more thorough review has not been possible given the brevity of the period between publication on Nov. 4, 2019 and the deadline for submitting comments for consideration by the SACC. For purposes of meeting the submission deadline, we have briefly identified in Appendix F and G examples of specific problematic passages in the draft Risk Evaluation that SIA would like to bring to the peer reviewers' attention.

**Summary**

As noted in the Introduction, commencing in late 2016, when EPA first identified NMP as one of the first 10 chemicals for risk evaluation, SIA has actively engaged with the Agency on an ongoing basis to provide information and insights for EPA personnel to enhance the Agency's understanding of the specialized conditions of use of NMP in the semiconductor industry. Among other things, SIA submitted several sets of detailed comments to EPA,[7] conducted extensive monitoring at semiconductor fabs, and shared information and data with EPA,[8] met with EPA officials in November 2017 to summarize the conditions of use of NMP at semiconductor fabs, and hosted a group of EPA officials in February 2019 to tour a semiconductor fab of a member company to provide

[7] 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).

[8] 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).

a first-hand understanding of the use and handling of chemicals at a fab. Unfortunately, it appears that much of the information and data SIA provided are not in the draft Risk Evaluation docket and may not have been thoroughly reviewed or were only partially considered by EPA personnel when preparing the draft Risk Evaluation. This reflects a deficiency which should be corrected before the final Risk Evaluation is prepared and this must be accomplished if the Agency is 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.

Throughout its interactions with EPA and as documented in the information provided to EPA, SIA has provided information sufficient to demonstrate that the highly complex processes involved in manufacturing advanced semiconductors, and the operational practices and engineering controls employed when handling chemicals at semiconductor fabs, effectively mitigate employee exposures to NMP at a fab. The air sampling data submitted to EPA serve to confirm that chemical handling procedures and the use of engineering controls and appropriate PPE successfully minimize worker exposure to NMP and other chemicals used in fab operations.

The considerable information SIA has provided should permit Agency reviewers to more clearly differentiate the semiconductor industry's conditions of use of NMP under the carefully controlled circumstances at semiconductor fabs from the conditions of use in other industrial and commercial use sites. SIA requests that SACC reviewers identify for EPA the many scientific benefits to be derived from evaluating the semiconductor sector's conditions of use of NMP separately from other industrial uses, such as "Solvent for Cleaning and Degreasing" or "Paint additives and coating additives not described by other codes."

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SIA is concerned that the erroneous conclusions reached by EPA in estimating worker exposure to NMP at semiconductor fabs have contributed to the Agency's draft Risk Evaluation preliminary findings concerning unreasonable risks to human health. The data and other materials SIA submitted to EPA do not support EPA's preliminary findings. We encourage the SACC to recognize that the weight of the data and information reasonably available to EPA supports the conclusion that the conditions of use of NMP at semiconductor fabs do present an unreasonable risk to the environment or to human health or worker safety. SIA urges the SACC to review carefully EPA's scientific approach, the entirety of the information and data SIA has made available to the Agency during the preceding 3 years, and to scrutinize the validity of EPA's modeling and the bases underlying the many unwarranted assumptions in the draft Risk Evaluation.