SIA-OMB Meeting on n-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (NMP): TSCA Risk Management Proposal

November 30, 2023



# Agenda

- Introductions and background on the Semiconductor Industry Association (SIA)
- Brief Review of SIA Engagement with EPA on NMP Use
  - Data on workplace practices provided throughout scoping and evaluation
  - Request for Correction submitted 2021; Denied without analysis in 2023
- Description of Industry Practices that Mitigate Worker Exposure
- Discussion of SIA Recommendation:
  - EPA Proposed Rulemaking Should Not Exceed Current Practices
  - Other Section 6 Actions Create Burdensome Workplace Controls
  - Such Burdens are Unnecessary in the Context of NMP Use by SIA Members



## Semiconductor Overview

 Semiconductor manufacturing occurs in highly automated fabrication facilities









### Risk Assessment: Highlights of SIA Engagement with EPA

SIA and its members provided information and data to EPA at various stages in the NMP Risk Evaluation and rulemaking processes, including:

- 1. Four fab tours
  - 1. Micron, Manassas, VA Jun. 13, 2023
  - 2. Intel, OR Mar. 2020
  - 3. Micron, Manassas, VA 2019
  - 4. Intel, AZ Apr 2018
- 2. Presentation given to SACC
- 3. Web meetings detailing the industry's uses of NMP and controls (engineering, administrative, PPE) in place to mitigate exposure
- 4. Air monitoring data (100+ datasets that SACC considered to be "exemplary") and associated work task descriptions (included risk management measures such as specific glove types, task frequency and duration information)
- 5. Pictures of tools used in a fab
- 6. Pictures of workers wearing cleanroom garments and personal protective equipment
- 7. Documentation of training to ensure proper use of gloves and other PPE
- 8. PBPK modeling using worst-case conditions of use for inputs showed no unreasonable risk to workers
- 9. Request for Correction submitted 2021; Denied without substantive analysis 2023



**Further Details** of NMP information provided by the Semiconductor Industry 2017-2022

Date	Submittal Type	Торіс	Submitter	Hyperlink
30-Jun-2022	Meeting	SIA-EPA Meeting on n-Methylpyrrolidone	SIA	
3-Jun-2021	Request for Correction	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]	SIA	https://www.epa.gov/quality/rfc-21004-n-methylpyrrolidone-nmp
3-Jun-2021	Report	Review of TSCA Section 6 Risk Evaluation of the Conditions of Use of NMP in the Semiconductor Industry prepared by Cardno Chemrisk, May 24, 2021	SIA	https://www.epa.gov/quality/rfc-21004-n-methylpyrrolidone-nmp
23-Feb-2021	Meeting	SIA-EPA Meeting on n-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (NMP), EPA-HQ- OPPT-2019-0236	SIA	https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0744 0003
12-Mar-2020	Meeting	Informal discussion with EPA (bulleted list submitted)	SIA	https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0743 0115
21-Jan-2020	Comments	Comments of the Semiconductor Industry Association (SIA) 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]	SIA	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019- 0236-0052
21-Jan-2020	Comments	Comments of Intel To the United States Environmental Protection Agency 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]	Intel	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019- 0236-0064
26-Nov-2019	SACC Comments	Semiconductor Industry Association, Nov. 2019. 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]	SIA	https://www.regulations.gov/comment/EPA-HQ-OPPT-2019-0236- 0031
5-Dec-2019	SACC Comments	Intel Comments to: Science Advisory Committee on Chemicals (SACC) On the Draft Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone (NMP)	Intel	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019- 0236-0037_
7-Nov-2019	Comments	Comments of Intel To the United States Environmental Protection Agency 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	Intel	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019- 0236-0064
22-Feb-2019	Report	N-Methylpyrrolidone Risk Management Measures and Worker Exposure Monitoring Results	SIA	NOTE: This study was determined to be of high quality by EPA assessors.
16-Jul-2018	Comments	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	SIA	https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0743- 0100
11-Apr-2018	Meeting	SIA Meeting with EPA: NMP Worker Exposure and Controls in the Semiconductor Industry	SIA	
8-Nov-2017	Meeting	SIA Meeting with EPA on NMP use in the semiconductor industry	SIA	
18-Sep-2017	Comments	SIA Comments To the EPA Docket on Methylene Chloride and N-Methylpyrrolidone (NMP), EPA Docket # EPA-HQ-OPPT-2016-0743	SIA	https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0743- 0063
19-May-2017	Comments	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	SIA	https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0231- 0593
15-Mar-2017	Comments	SIA Comments On the Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: N-Methylpyrrolidone (NMP), EPA-HQ-OPPT-2016-0743	SIA	https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0743- 0019



# Key Features of Data Provided

- SIA worked to provide EPA with data to demonstrate the industry's safe use of NMP
- SIA members conducted IH monitoring and provided 118 air sample results to the Agency [1]
- 113 were below detection limits (DL) only 5 samples showed concentrations above DL
  - Three of five were for 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
  - TWA concentration was 1.18 ppm for tanker truck offloading.
    - The measured exposure in this instance was 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 was 10 times lower than the AIHA's 10 ppm 8 hr. WEEL.
    - The virgin tanker unloading activity is conducted once per year and involves collection of a sample of the incoming virgin NMP for quality control analysis, during the tanker transfer process.
    - The process has since been modified to minimize the risk of exposure: (1) a ¼" fill line was installed exclusively to collect samples of the NMP for purity analysis and (2) the purged NMP from the unloading line is now routed and automatically collected in an enclosed container that is fitted with an activated carbon filter on the vent, to capture displaced NMP vapor.
    - Following these modifications, in 2021, additional personal air monitoring was completed for the modified virgin tank unload task. The TWA results of the NMP monitoring were all below the method detection limit (< 0.35 ppm and < 0.32 ppm).

Source: "N-Methylpyrrolidone Risk Management Measures and Worker Exposure Monitoring Results", 2019.



## Example IH data provided to EPA



Source: Intel Comments to: Science Advisory Committee on Chemicals, December 5th, 2019.

International

found here:

uv.de

**Occupational Exposure** 

Limits for NMP may be

https://limitvalue.ifa.dg

# Required PPE: Chemical Resistant Gloves, Chemical Resistant Gown, Chemical Goggles, Face Shield



Facilities Technician wearing PPE required for NMP container changes



Factory Technician wearing PPE required for maintenance and use of NMP

Depending on the potential exposure posed by the task, some of this PPE may not be used.

Sources: SIA Report: N-Methylpyrrolidone Risk Management Measures and Worker Exposure Monitoring Results, February 22, 2019. Intel Comments to: Science Advisory Committee on Chemicals, December 5th, 2019.

### Filter change:



Technician in cleanroom garments, face shield and gloves changing filter.

### Parts cleaning:



Enclosed and exhausted parts cleaning tool



Gloved worker uses hook to insert parts into NMP bath for cleaning

Source: SIA Report: N-Methylpyrrolidone Risk Management Measures and Worker Exposure Monitoring Results, February 22, 2019.

### **Risk Management: Semiconductor Industry Measures & Practices**

### **General Chemical Management**

#### **Engineering Controls**

- Design standards (SEMI S2 Equipment Design Standards & IBC, IFC Semi Specific Building Codes)
- Limited human interface
- Fail safe design
  - Ex: Exhaust ventilation and monitoring

#### **Administrative Controls**

- Equipment and facility start up inspections
- Chemical evaluation program and exposure assessment program
- Employee training
- Hazard communication
- Standard operating and maintenance procedures
- Personal Protective Equipment (PPE)

The semiconductor industry follows the standard NIOSH and OSHA hierarchy of controlling exposures to occupational hazards: Elimination, substitution, engineering controls, administrative controls and PPE.

Sources: SIA Meeting with EPA on NMP use in the semiconductor industry, Nov. 8, 2017. Meeting with EPA: NMP Worker Exposure and Controls in the Semiconductor Industry, April 11, 2018.

### **Preventing Exposure during Maintenance**

Tool emptied of chemical and purged prior to maintenance

Maintenance occurs at room temperature under local exhaust ventilation

Task-specific personal protective equipment (PPE) is required:

- Goggles
- Face shield
- Chemical resistant gloves
  - Only used for splash protection
- Chemical resistant apron
- Chemical resistant suit

## In summary, there is no exposed skin during maintenance activity

Source: Meeting with EPA: NMP Worker Exposure and Controls in the Semiconductor Industry, April 11, 2018.

Depending on the potential exposure posed by the task, some of this PPE may not be used.

## SIA Concerns with EPA's Risk Evaluation

- EPA's risk assessment concluded that NMP poses an "unreasonable risk" to workers involved in semiconductor manufacturing operations
  - SIA continues to believe this conclusion is incorrect and should be revised
  - EPA did not use the data provided by the SIA which the SACC determined to be "high-quality"
  - EPA assumptions about skin surface area and duration of exposure are incorrect and do not occur in the semiconductor industry.
- These deficiencies reflect a failure to meet scientific standards of TSCA Section 26
  - Best available information ignored in final Risk Evaluation
  - Weight of the evidence clearly demonstrates NMP is used safely at semiconductor fabs and mitigate worker exposures



# Proposed Risk Management Rule for NMP

- The proposed TSCA Section 6 rule for NMP should codify risk management practices consistent with existing practices in semiconductor industry manufacturing operations, as documented in the materials in the docket provided by SIA.
  - Engineering controls
  - Administrative controls
  - PPE
- Additional measures would add regulatory burdens and costs without advancing worker safety.



# Discussion/Questions



# **Supplemental Information**

# Selection and Use of PPE

- PPE is selected based on a hazard evaluation for the chemical, the SDS for the chemical, and the measured breakthrough characteristics of PPE materials
  - See Kirman (2020) on the NMP breakthrough characteristics of different gloves
- PPE training is provided that specifies the precise method of donning, using and removing PPE, as well as the inspection and care of PPE
- Work with NMP and use of PPE is only allowed if the employees have received comprehensive chemical safety training that requires passing grades on written tests that are administrated in the location specific language used at the manufacturing facility.
- If PPE contacts NMP then the PPE is discarded.



### **Representative Industry Training**

### Intel Required PPE Training

Training is required for all employees that use PPE.

### Employees

- must be knowledgeable of the hazards associated with their task
- when PPE is required
- what PPE is required
- the proper method of donning/doffing PPE and the proper disposal/maintenance requirements

Step	Action	Note/Results
1.	Don dry, clean chemical-resistant gloves over.	Place a 2 to 3 inch cuff in the glove to catch any drips which may run down the gloves.
2.	Don the chemical resistant gown by placing neck strap over the head and placing arms into the sleeves.	Place the gown sleeve over or under the glove cuff (either is acceptable) such that chemicals can not directly contact the skin in the event of a splash or liquids being on the glove. Tighten the sleeve of the gown over the glove using draw string and tie off (if applicable). Taping once around the wrist with clean room tape is recommended when reaching or when the sleeve is not snug around the glove cuff. Create a 2" tab for easy removal by folding the tape back onto itself.
3.	Put on protective eyewear, note splash resistant goggles required when handling corrosives.	Ensure that the fit is comfortable and is not too tight or too loose. Move head side to side and up and down to ensure that the goggles will not slip during usage.
	attach Dryden helmet face shield.	Keep safety glasses on; Chemical goggles are not required when wearing helmet.
4.	Don the face shield.	The face shield must be worn down over the face when ever there is the potential for splash to the face area i.e. pouring chemicals, wiping up freestanding liquids, etc.