



July 29, 2024

Submitted through <https://www.regulations.gov>

Ms. Clara Hull
Existing Chemicals Risk Management Division
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

RE: n-Methylpyrrolidone (NMP); Regulation Under the Toxic Substances Control Act (TSCA), EPA-HQ-OPPT-2020-0744

Dear Ms. Hull:

The Alliance for Automotive Innovation (Auto Innovators)¹ appreciates the opportunity to provide comments on EPA's draft risk management rule for n-Methylpyrrolidone (NMP).² Auto Innovators represents the auto manufacturing sector, including automakers that produce and sell approximately 95% of the new light-duty vehicles in the United States. Our mission is to work with policymakers to realize a future of cleaner, safer, and smarter personal transportation and to work together on policies that further these goals, increase U.S. competitiveness, and ensure sustainable, well-paying jobs for citizens throughout the country.

Our comments here reflect our concerns and recommendations for improving the workability of this proposed rule and request several clarifications of proposed requirements that are unclear to the regulated community. We also incorporate by reference our support for comments submitted by the Lithium-Ion Cell Manufacturers' Coalition (Coalition). The Coalition's comments focus on lithium cell manufacturing for electric vehicles (EVs), a critical use for the automotive sector.

We offer our support for a number of provisions in the draft, including a *de minimis* level for products containing NMP at concentrations less than 0.1% by weight that would not be subject to the proposed prohibitions and restrictions, and clear recognition that commercial uses of NMP in specialized electronics, such as lithium-ion battery manufacturing for use in electronic vehicles or semiconductor manufacturing, and the associated upstream manufacturing (including import) and processing uses should not be prohibited.

Our understanding of the proposed rule is that if finalized as drafted, it would:

1. Prohibit the manufacture (including import), processing, distribution in commerce, and use of NMP for five occupational conditions of use.

¹ From the manufacturers producing most vehicles sold in the U.S. to autonomous vehicle innovators to equipment suppliers, battery producers and semiconductor makers – Alliance for Automotive Innovation represents the full auto industry, a sector supporting 10 million American jobs and five percent of the economy. Active in Washington, D.C. and all 50 states, the association is committed to a cleaner, safer, and smarter personal transportation future. www.autosinnovate.org.

² 89 Fed. Reg. 51,134 (June 14, 2024).

2. Require container size limits and labeling requirements for the manufacture (including import), processing, and distribution in commerce of NMP for seven consumer uses.
3. Require prescriptive controls, including concentration limits and personal protective equipment (PPE) for seven occupational conditions of use.
4. Require strict workplace controls, including an NMP workplace chemical protection program (WCPP), that would include requirements to prevent direct dermal contact with NMP, for all other occupational conditions of use, including the commercial use of paints and coatings and paint, coating, and adhesive removers containing high concentrations of NMP in uses essential to the missions of the Department of Defense (DOD) and National Aeronautics and Space Administration (NASA).
5. Require a concentration limit on NMP for the import, processing, and distribution in commerce of one consumer use.
6. Establish recordkeeping and downstream notification requirements.³

In addition, EPA is proposing to define the following terms and codify them in 40 C.F.R. Part 751. These definitions include: “direct dermal contact,” “exposure group,” and “restricted area.”

Our comments below focus on:

- A. Auto Industry Uses of NMP
- B. Need for Clarification of Certain Proposed Restrictions and Requirements
- C. EPA’s Proposed *De Minimis* Level for Products but Not Articles
- D. Proposed New TSCA Definitions
- E. NMP-Specific PPE Requirements and Workplace Exposure Controls

A. Auto Industry Uses of NMP

Because of its low vapor pressure, NMP is generally not present in vehicles as a finished product. Any NMP used evaporates rapidly and is no longer present either as an inhalation or dermal exposure route. This lack of exposure potential applies to the two notable uses of NMP in our sector in terms of the auto as a final product.

First, NMP is used in lithium-ion battery cell manufacturing as a critical solvent in the production of cathode slurry. Specifically, NMP is present in the cathode mixing and cathode coating processes. The cathode mixing process involves adding raw powders and NMP to a mixer to create a slurry. NMP is added to the mixer through a closed loop automated piping system preventing exposure to employees. Once mixed, the cathode slurry is then automatically pumped to the cathode coating process. The cathode slurry is then applied mechanically to a moving aluminum foil via slot die and subsequently dried in an oven, removing the NMP and collecting it in an abatement system. Manual activities in the cathode mixing and coating processes include cleaning and maintenance of the system. Employees performing these tasks are required to wear NMP resistant gloves, coveralls, and respiratory protection to prevent exposure. The use of NMP in lithium battery manufacturing is well-covered in the comments submitted by the Lithium-Ion Cell Manufacturers’ Coalition, which we support.

³ 89 Fed. Reg. at 51,136.

Second, NMP is also used as a solvent in paint and coatings. Notably, some automotive coatings used during the manufacturing process may contain NMP as an additive at or above 45%. NMP is used in this scenario because there is no currently available substitute that delivers the required performance. Auto industry suppliers are looking into alternatives; however, at this time there is no drop-in replacement substance and identifying a substitute will require reformulation and requalification, which takes time. Substantial restrictions in the final rule on too short of a timeline could result in shortages and other supply interruptions and cost increases for auto manufacturers. The auto industry works to reduce any exposure from utilizing these coatings and paints. In the paint shops, paints are typically robotically applied in paint booths to mitigate potential employee exposure.

It is our understanding that the coating of the slurry material on lithium ion electrodes falls under the “Industrial and commercial use in lithium ion battery manufacturing” COU, and not under the COUs relating to coatings and paints, but would appreciate clarification from EPA, as Auto Innovators anticipates NMP concentrations in lithium ion battery manufacturing may exceed 45%.

The proposed rule proposes to require respirators whenever someone is working with NMP for paints or coatings for industrial uses identified in Section 791.211(b), with no exposure limit below which respirators are not required. Auto Innovators argues that EPA should identify an airborne concentration of NMP below which respirators would not be required because the risk of airborne exposure is sufficiently low.

B. Need for Clarification of Certain Proposed Restrictions and Requirements

The following prohibitions are of specific concern to our sector and are unclear in terms of scope: processing incorporation into articles in lubricants and lubricant additives in machinery manufacturing and processing; incorporation into articles in paint additives; and coating additives in transportation equipment manufacturing.

1. *Clarification of Descriptions of Conditions of Use*

Regarding “processing incorporation into articles in lubricants and lubricant additives in machinery manufacturing,” EPA defines this condition of use (COU) as a process or preparation:

when NMP is incorporated into articles in lubricants and lubricant additives in machinery manufacturing, and metal finishing operations conducted as part of machinery manufacturing. Metal finishing is a broad term used in industry to include a wide variety of processes that alter the surface of metal substrates, such as cleaning, coating, etching, and invasive quality testing.⁴

For “processing, incorporation into articles in paint additives and coating additives in transportation equipment manufacturing,” EPA defines this COU as:

the process or preparation when NMP is incorporated into articles in paints and coating additives in transportation equipment manufacturing. Transportation equipment manufacturing includes motor vehicle parts motor vehicle body and trailer

⁴ 89 Fed. Reg. at 51,146.

manufacturing, aerospace product and parts manufacturing, railroad rolling stock manufacturing, and ship and boat building.⁵

We find these two conditions of use confusing as phrased and are not sure exactly what they are intended to describe. We reviewed the final risk evaluation⁶ for more specifics on these COUs as well as the 2016 Chemical Data Reporting (CDR) data for NMP but can find no additional information on the specific uses that have triggered EPA's concerns. For example, if accurate Auto Innovators suggests that EPA rephrase the first COU as "when NMP is incorporated into lubricants and lubricant additives **in articles** in machinery manufacturing, and metal finishing operations conducted as part of machinery manufacturing." Otherwise, as written, the sentence suggests that an article could possibly be incorporated into a lubricant.

EPA acknowledged that for some of these COUs, EPA has not identified any current use of NMP (e.g., in antifreeze, de-icing products, and lubricants)⁷ and is asking for comment and any relevant use data. Without a more meaningful description of the above COUs, it is difficult for us to supply such information.

Finally, we also request that EPA clearly explain how its rule would apply to articles. It appears articles are mentioned in specified COUs, but otherwise it appears that EPA did not assess articles. It is therefore not immediately clear to Auto Innovators how this rule might otherwise apply to articles, and Auto Innovators suggests that EPA clearly state that articles are not covered by the risk management rule except as specifically specified for certain COUs.

2. Clarification of EPA's Requirement for Labeling of Imported Products

EPA is proposing to require all importers, processors, and distributors in commerce of the NMP-containing products for the COUs not prohibited to provide a label securely attached to each product. Label information would be required to be prominently displayed in an easily readable font size and contain a larger warning paragraph, including the sentence "This product is only for sale in containers of 16 ounces or less and is for consumer use only" in bold print or a larger font for emphasis.⁸

We request clarification on EPA's expectations for who will generate and apply this label and when it must be present. For example, for imported products must the label be present when the import is received in the United States? In which case the external supplier will need to apply the required label. Or will the importer be required to apply the label before the product is released to the importing entity? Or can the product be released to the importer and the label applied before further distribution in commerce? Further clarification of this requirement would be helpful. Further, both the Consumer Product Safety Commission and the California Office of Environmental Health Hazard Assessment require labeling of NMP. Any labeling requirements instituted by EPA should be

⁵ 89 Fed. Reg. at 51,146.

⁶ U.S. Environmental Protection Agency, N-Methylpyrrolidone (NMP): Unreasonable Risk Determination (Dec. 2022), available at https://www.epa.gov/system/files/documents/2022-12/NMP_Final%20Revised%20RD_12-12-22.pdf.

⁷ 89 Fed. Reg. at 51,137.

⁸ 89 Fed. Reg. at 51,152.

consistent with those requirements and should, as a practical matter, take into consideration the space available for such labels—for example on a 16-ounce container.

C. EPA's Proposed *De Minimis* Level for Products but Not Articles

EPA's final rule adopts a *de minimis* threshold of 0.1% for products to account for impurities and the unintended presence of NMP. Because it is not clear whether EPA is prohibiting the incorporation of NMP into articles, we request that EPA provide a *de minimis* level for articles as well as products by including them in the following provision:

To aid the regulated community with implementing the prohibitions and restrictions, and to account for *de minimis* levels of NMP as an impurity in products, EPA is proposing that products containing NMP at concentrations less than 0.1% by weight would not be subject to the proposed prohibitions and restrictions. EPA has determined that the prohibitions and restrictions would only be necessary for products containing NMP at levels equal to or greater than 0.1% by weight to eliminate the unreasonable risk of injury resulting from inhalation and dermal exposures from NMP-containing products during occupational and consumer conditions of use.⁹

EPA's conclusion that most consumer uses do not contribute to the unreasonable risk for NMP, largely due to the generally low concentration of NMP in consumer products, applies equally to NMP uses in article manufacturing and processing.

As with products, NMP's potential processing in the manufacture of articles in practice poses minimal risk to human health. Based on NMP's low vapor pressure and its use as a solvent, NMP evaporates rapidly. Additionally, NMP exposures in the workplace can be further prevented by industrial ventilation and with readily available PPE. Exposure to NMP when present in our facilities is controlled through the use of gloves, aprons, and goggles, as well as engineering controls.

To further confound this proposed restriction we note that EPA proposed to "require that import, processing, and distribution in commerce (including by retailers) of NMP and formulated NMP-containing products intended for consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants be limited to a concentration of NMP no greater than 45%."¹⁰ We question why this proposed concentration limit is not appropriately applied to occupation uses where PPE and other workplace controls are in place.

If EPA is concerned about the potential presence of NMP in finished articles, although we believe the exposure potential for this COU is minimal, we request that in addition to making available a *de minimis* level EPA include this COU under permitted uses with the inclusion of EPA's proposed WCPP requirements. This dual approach would address any potential exposures that may occur.

D. Proposed New TSCA Definitions

As a general matter we request that EPA issue separate notices when proposing and finalizing definitions that apply broadly to the TSCA program as opposed to a specific chemical. By

⁹ 89 Fed. Reg. at 51,150.

¹⁰ 89 Fed. Reg. at 51,158.

embedding these proposed definitions in chemical-specific rulemaking, they may be overlooked by industries or other stakeholders that have no interest in the specific chemical at issue. This creates a lack of transparency and limits input to EPA on key TSCA regulation-writing.

Direct dermal contact means direct handling of a chemical substance or mixture or skin contact with surfaces that may be contaminated with a chemical substance or mixture.¹¹

We recommend that this definition include a reference to any *de minimis* level associated with the chemical and an exclusion when appropriate PPE is used, especially in cases where a WCPP is not required.

Exposure group means a group consisting of every person performing the same or substantially similar operations in each work shift, in each job classification, in each work area where exposure to chemical substances or mixtures is reasonably likely to occur.¹²

This is an overly broad definition and needs to be amended to say “where exposure to chemical substances or mixtures **has been demonstrated to occur.**”

Restricted area means an area established by the regulated entity to demarcate areas where direct dermal contact with a specific chemical substance may occur.¹³

This definition needs further clarification pursuant to our suggested changes for the term “direct dermal contact.” It appears a “restricted area” would be required where engineering controls can’t eliminate the risk of dermal contact; Auto Innovators feels this may be overly inclusive and suggests a more restrictive application.

Additionally, EPA is not proposing to incorporate the descriptions and definitions for those conditions of use evaluated in the 2020 Risk Evaluation for NMP that would not be prohibited. We believe that incorporating those determinations would be appropriate and would aid in addressing preemption issues.

E. NMP-Specific PPE Requirements and Workplace Exposure Controls

As Auto Innovators has reviewed the series of TSCA risk management proposals that have been issued over the past few months, we note that EPA has proposed PPE requirements and workplace exposure controls that appear to be chemical-specific. It is important for EPA to understand that our members develop risk management programs (PPE and workplace controls) that are designed to provide protection for workers from not just one chemical, but from any chemical where there may be the potential for exposure. As such, our industry’s WCPPs may not align directly with EPA’s proposed requirements. We request that EPA acknowledge in this and other rules that WCPPs are designed to address all potential worker exposure scenarios. We also request that EPA acknowledge the high degree of automation and use of robotics and totally enclosed processes that are in place in our facilities. On multiple site visits arranged for EPA staff, we have demonstrated the effective use of these and other worker protection safety measures.

¹¹ 89 Fed. Reg. at 51,188.

¹² 89 Fed. Reg. at 51,188.

¹³ *Ibid*

We additionally recommend that EPA lengthen their implementation timelines to 18 to 24 months. Auto Innovators finds that 12 months before implementation of a WCPP is not sufficient, especially given coordination between Occupational Safety and Health Administration and EPA requirements.

Conclusion

Our goal in submitting these comments is to request clarification on COU restrictions referenced in the draft rule and to offer our recommendations on managing any potential risks from the NMP uses in our facilities. These recommendations are based on our in-depth knowledge of our operations, our in-place adherence to the industrial hygiene hierarchy and our worker protection requirements that routinely exceed all federal and state requirements. Our request for a *de minimis* level for articles is predicated on EPA's response as to whether imported articles are part of EPA's proposed ban, although we believe this request has a broader relevance for any risk management rule that may include restrictions on articles. Our recommendations on definitions also impact not only the workability of this proposal but all TSCA risk management proposals that rely on these definitions.

If Auto Innovators can be of further assistance, please feel free to contact me at 202-326-5511 or cpalin@autosinnovate.org.

Sincerely,



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