

Environmental Justice Consultation Fact Sheet:

Proposed Rulemaking Under TSCA Section 6(a) for n-Methylpyrrolidone (NMP)

Background Information for this Consultation

EPA is developing proposed regulations under section 6(a) of the Toxic Substances Control Act (TSCA) to address the unreasonable risk presented by n-methylpyrrolidone (NMP) under the conditions of use. EPA made the determination of unreasonable risk in the final risk evaluation for NMP, completed in December 2020. EPA is initiating this action to address the unreasonable risks presented by NMP.

EPA is seeking input from communities during this consultation and encourages participation and comments to inform EPA's upcoming proposed regulation. Input from all stakeholders is critical to the risk management process. EPA is committed to developing risk management actions for chemicals in a way that is transparent and includes proactive, meaningful outreach and education with the public and other stakeholders.

While outreach and stakeholder engagement on risk management activities for this chemical will continue to move forward, EPA is actively reviewing the final risk evaluation to ensure it uses the best available science and protects human health and the environment, in accordance with the Executive Orders and other direction provided by the Biden-Harris Administration. The Agency will keep stakeholders updated as decisions are made, and next steps are determined.

NMP and EPA's Risk Evaluation

NMP has a wide range of uses, including in the production of paints and coatings, as a solvent for cleaning and degreasing, and in the manufacture of electronics. There are also a variety of consumer and commercial products that contain NMP, such as adhesives and sealants, as well as adhesive removers, automotive care products, and paints and coatings.

EPA evaluated 37 conditions of use of NMP, and, in the final risk evaluation published on December 30, 2020, determined that 26 conditions of use present an unreasonable risk. This includes unreasonable risks to workers when domestically manufacturing or importing the chemical, processing the chemical for a variety of uses, and when used in a variety of industrial and commercial applications. This also includes unreasonable risks to consumers for one consumer use.

For risks to the environment, EPA assessed NMP exposures to aquatic organisms and has determined that NMP does not present an unreasonable risk of injury to the environment from all conditions of use, based on the risk estimates, the environmental effects of NMP, the exposures, physical-chemical properties of NMP and consideration of uncertainties.

For the conditions of use found to present an unreasonable risk of injury to human health, EPA's determination is based on unreasonable risk to workers during occupational exposures, and to consumers during exposures to one consumer use.

EPA found that there was unreasonable risk of developmental toxicity (toxic effects to the

developing embryo or fetus) from acute (single-day) inhalation and dermal (through the skin and uptake of vapor through skin) exposures, and reproductive toxicity (decreased male fertility) from chronic (long-term) inhalation and dermal exposures to NMP.

The conditions of use with unreasonable risks include manufacturing (including import), processing in a formulation, industrial and commercial uses such as in paints, coatings, and adhesives, in electronic manufacturing, and the consumer use in adhesives and sealants.

The risk evaluation was conducted pursuant to TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to evaluate the manufacture (including import), processing, distribution in commerce, use, and disposal of existing chemical substances and identify those conditions of use which present unreasonable risks to health or the environment. Public comments on and external scientific peer review of the draft risk evaluation¹ informed the development of the final risk evaluation. The final risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0236, with additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0743, on www.regulations.gov. More information about the final risk evaluation is at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-n-methylpyrrolidone-nmp>.

Unreasonable Risks

EPA's unreasonable risk determinations for conditions of use of NMP are based on unreasonable risk of injury to health for workers during occupational exposures, and for consumers during exposures to one consumer use. EPA's unreasonable risk determinations are due to non-cancer effects from developmental toxicity from acute inhalation and dermal (including uptake of vapor through skin) exposures and from reproductive toxicity from chronic inhalation and dermal (including uptake of vapor through skin) exposures to NMP.

The list below shows the conditions of use of NMP that EPA has determined present an unreasonable risk of injury to human health.

Conditions of Use of NMP that Present an Unreasonable Risk

Manufacturing that Presents an Unreasonable Risk
<ul style="list-style-type: none">• Domestic manufacture• Import
Processing that Present an Unreasonable Risk
<ul style="list-style-type: none">• As a reactant or intermediate in plastic material and resin manufacturing and other non-incorporative processing

¹ In 2016, the Office of Pollution Prevention and Toxics (OPPT) identified and selected NMP as one of the first 10 chemicals for risk evaluation under section 6 of TSCA. EPA published the scope of the risk evaluation document in June 2017, the NMP problem formulation document in June 2018, and the NMP draft risk evaluation in November 2019. EPA held a peer review meeting of the Science Advisor Committee on Chemicals (SACC) on the draft risk evaluation of NMP on December 5-6, 2019.

- Incorporation into a formulation, mixture or reaction product in multiple industrial sectors
- Incorporation into articles in lubricants and lubricant additives in machinery manufacturing
- Incorporation into articles in paint additives and coating additives not described by other codes in transportation equipment manufacturing
- Incorporation into articles as a solvent (which becomes part of a product formulation or mixture) including in textiles, apparel and leather manufacturing
- Incorporation into articles in other sectors, including in plastic product manufacturing
- Repackaging in wholesale and retail trade
- Recycling

Industrial and Commercial Uses that Present an Unreasonable Risk

- Industrial and commercial use in paints, coatings, and adhesive removers
- Industrial and commercial use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes, and powder coatings in surface preparation
- Industrial and commercial use in paint additives and coating additives not described by other codes in computer and electronic product manufacturing in electronic parts manufacturing
- Industrial and commercial use in paint additives and coating additives not described by other codes in computer and electronic product manufacturing for use in semiconductor manufacturing
- Industrial and commercial use in in paint additives and coating additives not described by other codes in multiple manufacturing sectors
- Industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing
- Industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing for use in semiconductor manufacturing
- Industrial and commercial use in processing aids, specific to petroleum production in petrochemical manufacturing, in other uses in oil and gas drilling, extraction and support activities, and in functional fluids (closed systems)
- Industrial and commercial use in adhesives and sealants including binding agents, single component glues and adhesives, including lubricant adhesives, and two-component glues and adhesives including some resins
- Industrial and commercial use in other uses in anti-freeze and de-icing products, automotive care products, and lubricants and greases
- Industrial and commercial use in other uses in metal products not covered elsewhere, and lubricant and lubricant additives including hydrophilic coatings
- Industrial and commercial use in other uses in laboratory chemicals
- Industrial and commercial uses in other uses in lithium ion battery manufacturing
- Industrial and commercial use in other uses in cleaning and furniture care products, including wood cleaners and gasket removers

Consumer Use that Presents an Unreasonable Risk
<ul style="list-style-type: none"> • Consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants

Disposal that Presents an Unreasonable Risk
<ul style="list-style-type: none"> • Disposal

Reason for This Action

Section 6 of TSCA requires EPA to address unreasonable risks that EPA has determined are presented by a chemical substance under the conditions of use. The risk evaluation was conducted pursuant to TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to evaluate the manufacture (including import), processing, distribution in commerce, use, and disposal of existing chemical substances and identify those conditions of use that present unreasonable risks to health or the environment. Following a risk evaluation carried out under the authority of TSCA section 6, EPA has determined that NMP presents an unreasonable risk of injury to health.

EPA is now moving to risk management for NMP, the next step in the process required by TSCA. With stakeholder input, EPA is developing ways to address the unreasonable risks identified and has one year to propose and take public comments on risk management actions.

Risk Mitigation Approaches Under Section 6

Under TSCA section 6(a), 15 U.S.C. § 2605(a), “If the Administrator determines ... that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 18, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk.”

The table below summarizes regulatory options available under TSCA section 6(a).

The proposed regulation under development would address the unreasonable risk presented by NMP under each condition of use listed above. EPA is currently in the early stages of the rulemaking process and is interested in receiving information during this consultation to inform the development of regulatory options.

Options under TSCA Section 6(a)

TSCA Section	Option
6(a)(1)	A requirement (A) prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.
6(a)(2)	A requirement (A) prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.
6(a)(3)	A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.
6(a)(4)	A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.
6(a)(5)	A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.
6(a)(6)	(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.
6(a)(7)	A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such risk of injury, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Potential Environmental Justice Impact

EPA recognizes that decisions concerning TSCA section 6(a) regulations have consequences for stakeholders concerned about environmental justice issues. Environmental justice communities may be affected to the extent that individuals in these communities engage in the manufacturing, processing, industrial uses, commercial uses and disposal of NMP that EPA determined present an unreasonable risk.

In addition to general comments, EPA requests input on any disproportionate public health or economic impacts that the unreasonable risks presented by NMP may have in the context of environmental justice issues.

Opportunity for Participation in Environmental Justice Consultation

E.O. 12898 aims to focus federal attention on the environmental and human health effects of federal actions on minority and low-income populations with the goal of achieving environmental protection for all communities. During this consultation process, EPA invites members of the public and national, local and non-governmental organizations, communities, and other interested stakeholders to participate in this process by attending the consultation sessions and providing written comments. After the conclusion of the Environmental Justice consultation process, all stakeholders are encouraged to also participate in the public comment process.

Additional Outreach

There are several opportunities for public and stakeholder engagement throughout the risk management process. This includes required consultations with certain groups, public meetings/webinars, one-on-one meetings with stakeholders, and public comment periods.

EPA is carrying out engagement opportunities in compliance with several executive orders. Some consultations will be open to the public, and in the interest of promoting transparency and encouraging participation, the dates and point of contacts for those consultation meetings will be listed on <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities>.

Also, in support of EPA's commitment to implementing TSCA in an open and transparent manner, the Agency has organized webinars on current risk management activities, including rulemakings such as this one. The purpose of these stakeholder engagement events is to educate stakeholders on various proposals, announcements, or policy decisions, as well as to provide a forum for the public to provide feedback or input during the risk management process.

EPA also holds meetings with stakeholders to educate them about TSCA implementation, listen to feedback, and obtain information that will benefit EPA's work. Finally, as part of the rulemaking process, EPA will solicit and obtain comments on proposed rules. To do this, the Agency will open a public comment period for each proposed rule. These public comment periods relevant to TSCA implementation are announced by the Agency through press releases/listservs and by publication in the Federal Register.

Additional Information

For more information on this consultation or the rulemaking under TSCA section 6 for NMP contact: Amanda Hauff, Office of Chemical Safety and Pollution Prevention's National Environmental Justice Program Manager, hauff.amanda@epa.gov, 202-566-0603 or Eileen Sheehan, Office of Pollution Prevention and Toxics, Sheehan.Eileen@epa.gov, 415-972-3287.

Risk management and upcoming outreach for NMP:

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-n-methylpyrrolidone-nmp>

NMP Final Risk Evaluation:

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-n-methylpyrrolidone-nmp>

US EPA Nontechnical Summary of the Risk Evaluation for NMP:

https://www.epa.gov/sites/production/files/2020-12/documents/nmp_non-technical_summary.pdf