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Environmental Protection Agency

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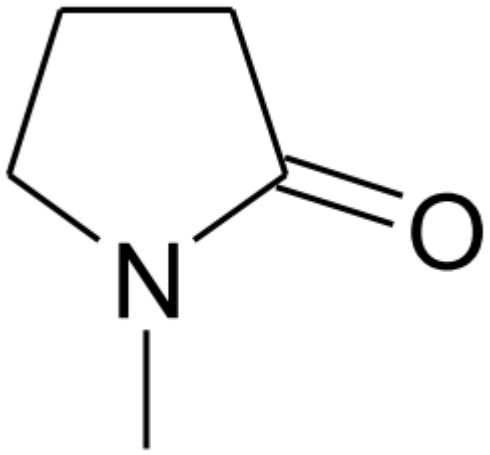
Office of Chemical Safety and
Pollution Prevention

Non-Technical Summary of the Risk Evaluation for n-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-)

CASRN: 872-50-4



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BACKGROUND

- The TSCA risk evaluation for n-methylpyrrolidone (NMP) was issued in December 2020.
- Uses for NMP include domestic manufacturing and import; processing as a reactant or intermediate or into a formulation, mixture or reaction product; repackaging and recycling; a variety of industrial and commercial uses including as a paint and coating additive and paint and coating removers, a solvent in a variety of applications such as electrical equipment manufacturing, a processing aid in a variety of applications including petrochemical manufacturing, and for cleaning or degreasing. A variety of consumer and commercial products use NMP in formulations including paints and coatings, paint and coating removers, adhesives and sealants, and automotive and furniture cleaning products.
- The total annual aggregate production volume reported under the Chemical Data Reporting rule for the 2020 period indicates between 100 to 250 million pounds of NMP were manufactured (including imported) in the United States.

ACTION

- EPA is releasing a final revision to the risk determination on NMP with an order withdrawing the TSCA section 6(i)(1) order previously included in the December 2020 risk evaluation. This action follows issuance of a draft revised risk determination that EPA issued for comment in July 2022 (87 FR 39511). EPA has determined that NMP presents an unreasonable risk of injury to health under its conditions of use.
- This final risk evaluation, which includes the 2020 risk evaluation and a 2022 final revised unreasonable risk determination, is conducted pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to prioritize and evaluate the risk of existing chemicals to determine whether a chemical presents an unreasonable risk of injury to health or the environment under the conditions of use. Under TSCA, if a chemical is determined to present an unreasonable risk, then EPA will propose risk management regulatory action to the extent necessary so that the chemical substance no longer presents an unreasonable risk.
- The 2020 risk evaluation, supplemental materials, 2022 revised unreasonable risk determination and corresponding response to public comments can be found in dockets EPA-HQ-OPPT-2019-0236 and EPA-HQ-OPPT-2016-0743 on www.regulations.gov.
- NMP was selected in 2016 as one of the first 10 chemicals for risk evaluation under section 6 of TSCA.

KEY POINTS

- EPA has identified risks for non-cancer adverse effects from acute and chronic inhalation and dermal exposures to NMP. In the NMP risk characterization developmental effects were identified as the best representative endpoint for non-cancer adverse effects from acute inhalation and dermal exposures, and reproductive effects were identified as the best representative endpoint for non-cancer adverse effects from chronic inhalation and dermal exposures for all conditions of use.
- Additional risks associated with other adverse effects (*e.g.*, liver toxicity, kidney toxicity, immunotoxicity, neurotoxicity, irritation and sensitization) were identified for acute and chronic exposures.
- Public comments and external scientific peer review informed the development of the NMP final risk evaluation. EPA published the NMP final revised unreasonable risk determination in

December 2022, the NMP draft revised unreasonable risk determination in July 2022, the NMP risk evaluation in December 2020, the NMP draft risk evaluation in November 2019 (for a 60-day public comment period), the NMP problem formulation document in June 2018, and the scope document in June 2017.

- Additionally, EPA held a peer review meeting of the Science Advisory Committee on Chemicals (SACC) on the draft risk evaluation of NMP on December 5-6, 2019.
- In the revised unreasonable risk determination for NMP, EPA is making an unreasonable risk determination for NMP as a whole chemical substance, rather than taking a condition of use-specific approach. The whole chemical approach is appropriate for NMP because there are benchmark exceedances for a substantial number of conditions of use for human health and there are irreversible health effects associated with NMP exposures.
- After evaluating 37 conditions of use, EPA determined that NMP presents an unreasonable risk to human health under its conditions of use based on risk of injury to health of workers during occupational exposures and to consumers.
- In addition, EPA is revising the assumption that workers always and properly use personal protective equipment (PPE), although EPA does not question public comments received regarding the occupational safety practices often followed by industry. Information on the use of PPE as a means of mitigating risk will be considered during the risk management phase. Removing the assumption that workers wear PPE means that three additional conditions of use in addition to the original 26 drive the unreasonable risk for NMP, and for five conditions of use, acute effects in addition to chronic effects also drive the unreasonable risk to workers.
- Overall, 29 of the 37 conditions of use evaluated drive the NMP whole chemical unreasonable risk determination due to risks identified for human health. These conditions of use include but are not limited to: domestic manufacturing and import; processing as a reactant or intermediate or into a formulation, mixture or reaction product; repackaging and recycling; a variety of industrial and commercial uses including as a paint and coating additive and paint and coating removers, a solvent in a variety of applications such as electrical equipment manufacturing, a processing aid in a variety of applications including petrochemical manufacturing, and for cleaning or degreasing. A variety of consumer and commercial products use NMP in formulations including paints and coatings, paint and coating removers, adhesives and sealants, and automotive and furniture cleaning products.
- The conditions of use that do not drive EPA's unreasonable risk determination for NMP include distribution in commerce; consumer use in paint and coating removers; adhesive removers; lacquers, stains, varnishes, primers and floor finishes; paint and coating additives; automotive care products; cleaning and furniture care products; and lubricant and lubricant additives including hydrophilic coatings.
- For NMP the exposure pathways that were or could be regulated under another EPA-administered statute were not fully assessed as part of the final risk evaluation (see section 1.4.2 of the December 2020 NMP Risk Evaluation). For NMP, some exposure pathways received only a screening-level analysis. During problem formulation, EPA conducted a first-tier screening analysis for the ambient air pathway to near field populations downwind from industrial and commercial facilities releasing NMP which indicated low risk. In the December 2020 NMP Risk Evaluation EPA conducted a first-tier analysis to estimate NMP surface water concentrations and did not identify risks from incidental ingestion or dermal contact during swimming. This resulted in the ambient air and drinking water pathways for NMP not being fully assessed in the risk evaluation published in December 2020. EPA is conducting a

screening approach to assess risks from the air and water pathways for several of the first 10 chemicals, including NMP. The goal of the recently-developed screening approach is to remedy this exclusion and to determine if there are risks that were unaccounted for in the NMP risk evaluation. EPA expects to describe its findings regarding the chemical-specific application of this screening-level approach in the forthcoming proposed rule under TSCA section 6(a) for NMP.
- EPA did not identify risks of injury to the environment that drive the unreasonable risk determination for NMP.
- As noted above, EPA is releasing a final revision to the unreasonable risk determination with an order withdrawing the TSCA section 6(i)(1) order previously included in the December 2020 risk evaluation. EPA is also releasing a document with response to public comments received on the draft revised risk determination for NMP published in July 2022.

NEXT STEPS
- EPA has issued the final risk evaluation (2020 risk evaluation and 2022 revised risk determination) for NMP, meeting the requirements set forth in TSCA section 6(b) for chemical risk evaluations. EPA is now initiating the process to address the unreasonable risk identified. Following the issuance of the final risk evaluation, EPA will address, by rule, the unreasonable risk identified. The public will have an opportunity to comment on a proposed rule before EPA issues a final rule.

SUMMARY OF UNREASONABLE RISK DETERMINATION
EPA has determined that NMP presents an unreasonable risk of injury to human health under the conditions of use.

EPA's unreasonable risk determination for NMP is driven by risks associated with the following conditions of use, considered singularly or in combination with other exposures:
- Manufacturing – Domestic manufacture;
- Manufacturing – Import;
- Processing as a reactant or intermediate in plastic material and resin manufacturing and other non-incorporative processing;
- Processing for incorporation into a formulation, mixture, or reaction product in multiple sectors;
- Processing for incorporation into articles—in lubricants and lubricant additives in machinery manufacturing;
- Processing for incorporation into articles in paint additives and coating additives not described by other codes in transportation equipment manufacturing;
- Processing for incorporation into articles as a solvent (which become part of product formulation or mixture), including in textiles, apparel, and leather manufacturing;
- Processing for incorporation into articles in other sectors, including in plastic product manufacturing;
- Processing in recycling;
- Processing for repackaging (wholesale and retail trade);
- 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, powder coatings (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 paint additives and coating additives not described by other codes in computer and electronic product manufacturing in semiconductor manufacturing;
- Industrial and commercial use paint additives and coating additives 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 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 additives, 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 metal products not covered elsewhere and lubricant and lubricant additives including hydrophilic coatings;
- Industrial and commercial uses in other uses in laboratory chemicals;
- Industrial and commercial uses in other uses in lithium ion battery manufacturing;
- Industrial and commercial uses in other uses in cleaning and furniture care products including wood cleaners and gasket removers;
- Industrial and commercial use in ink, toner, and colorant products (printer ink; inks in writing equipment);
- Industrial and commercial use in other uses in soldering materials;
- Industrial and commercial use in other uses in fertilizer and other agricultural chemical manufacturing in processing aids and solvents;
- Consumer use in adhesives and sealants (glues and adhesives including lubricant adhesives); and
- Disposal.

The following conditions of use do not drive EPA's unreasonable risk determination for NMP:

- Distribution in commerce;
- Consumer use in paint and coating removers;
- Consumer use in adhesive removers;
- Consumer use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes;
- Consumer use in paint additives and coating additives not described by other codes in paints and arts and crafts paints;
- Consumer use in other uses in automotive car products;
- Consumer use in other uses in cleaning and furniture care products, including wood cleaners and gasket removers; and

- Consumer use in other uses in lubricant and lubricant additives, including hydrophilic coatings.

EPA is not making condition of use-specific risk determinations for these conditions of use, is not issuing a final order under TSCA section 6(i)(1) for these conditions of use, and does not consider the revised risk determination for NMP to constitute a final agency action at this point in time.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory action to the extent necessary so that NMP no longer presents an unreasonable risk. EPA expects to focus its risk management action on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk.