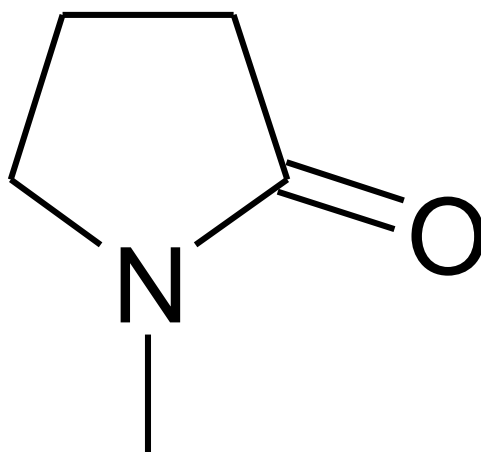




n-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (NMP) Final Risk Evaluation

Non-technical Summary

CASRN: 872-50-4



December 2020

ACTION

- EPA is releasing the final risk evaluation on n-methylpyrrolidone (NMP). After evaluating 37 conditions of use of NMP, EPA has determined that NMP presents an unreasonable risk under 26 conditions of use. This includes an unreasonable risk 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 conditions of use. This also includes an unreasonable risk to consumers from one consumer use. NMP does not pose an unreasonable risk under distribution in commerce or in a variety of industrial and commercial and consumer applications. EPA also determined that NMP does not present an unreasonable risk to the environment and general population.
- This final risk evaluation 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 safety 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 must regulate the substance to address the unreasonable risk.
- The final risk evaluation and supplemental materials can be found in docket EPA-HQ-OPPT-2019-0236 on www.regulations.gov.
- NMP was selected in 2016 as one of the first 10 chemicals for risk evaluation under section 6 of TSCA.
- Public comments and external scientific peer review informed the development of the NMP final risk evaluation. EPA published the NMP draft risk evaluation in November 2019, the NMP problem formulation document in June 2018, and the scope document in June 2017.

KEY POINTS

- After evaluating 37 conditions of use of NMP, EPA determined that NMP presents an unreasonable risk under 26 conditions of use. This includes an unreasonable risk of injury to health of workers during occupational exposures, and to consumers during one consumer use.
- These unreasonable risks of injury to health include developmental effects from acute inhalation and dermal exposures, and reproductive effects from chronic inhalation and dermal exposures.
- The conditions of use with unreasonable risks include domestic manufacturing and import; processing as a reactant or intermediate or into a formulation, mixture or reaction product; in articles; repackaging and recycling; a variety of industrial and commercial uses including as a paint and coating additive and solvent for cleaning or degreasing, adhesives and sealants, anti-freeze and de-icing products, metal products including hydrophilic coatings, lithium ion battery manufacturing, laboratory chemicals, and cleaning and furniture care products; and consumer use in adhesives and sealants.
- The conditions of use that EPA determined do not present an unreasonable risk include distribution in commerce; industrial and commercial use in ink, toner, and colorant products; soldering; fertilizer and other agricultural chemical manufacturing, and 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.

- EPA released the draft risk evaluation for NMP in November 2019 for a 60-day public comment period. Additionally, EPA held a peer review meeting of the Science Advisory Committee on Chemicals on the draft risk evaluation of NMP on December 5-6, 2019. The report is in the TSCA Science Advisory Committee on Chemicals docket (EPA-HQ-OPPT-2019-0236). Along with the final risk evaluation, EPA is releasing a document that provides a response to public and peer review comments.

BACKGROUND

- NMP has a wide range of uses in industry and consumer and commercial products. NMP is widely used as a solvent in the manufacture and production of electronics, petroleum products, pharmaceuticals, polymers and other specialty chemicals. The total aggregate production volume reported under the Chemical Data Reporting rule for the 2016 period indicates over 160 million pounds of NMP were manufactured (including imports) in the United States.
- In 2015, prior to amended TSCA, EPA published an [NMP risk assessment](#) that covered a subset of uses with high potential for exposure to consumers and workers. This NMP risk assessment identified non-cancer risks. The final risk evaluation assesses a much broader range of conditions of use than the prior risk assessment.
- Evaluation and risk management steps for the NMP final risk evaluation:
 - EPA has issued the final risk evaluation for NMP, meeting the requirements set forth in TSCA section 6. EPA is now initiating the process to address the unreasonable risks identified in the final risk evaluation. EPA has two years following the issuance of the final risk evaluation to address, by rule, the unreasonable risks identified.
- State actions on NMP:
 - Some states have taken actions on NMP. New Hampshire regulates NMP as a toxic air pollutant, and Vermont regulates NMP as a hazardous air contaminant. Several states, including Washington, Vermont and Oregon have adopted reporting laws for chemicals, including NMP, in children's products. Minnesota lists NMP as a chemical of concern to children. Massachusetts, New Jersey and Pennsylvania list NMP under their State Right-to-Know laws.
 - California has taken several actions on NMP. California has a Permissible Exposure Limit for NMP of 1 ppm as an 8-hour time-weighted average (TWA) along with a skin notation. California lists NMP on Proposition 65 due to reproductive toxicity and has established a Maximum Allowable Dose Level (MADL) for inhalation and for dermal exposure. California Department of Toxic Substances Control's Safer Consumer Products Program listed NMP as a Candidate Chemical for developmental and reproductive toxicity and in 2018 proposed to list Paint and Varnish Strippers and Graffiti Removers Containing NMP as a priority product.

NEXT STEPS

- EPA has issued the final risk evaluation for NMP, meeting the requirements set forth in TSCA section 6(b). EPA is now initiating the process to address the unreasonable risks identified. EPA has two years following the issuance of the final risk evaluation to address, by rule, the unreasonable risks identified.

SUMMARY OF UNREASONABLE RISK DETERMINATIONS

EPA has determined that the following conditions of use of NMP do not present an unreasonable risk of injury to health or the environment. These determinations are considered final agency action and are being issued by order pursuant to TSCA Section 6(i)(1).

Conditions of Use that Do Not Present an Unreasonable Risk

- Distribution in commerce
- Industrial and commercial use in ink, toner and colorant products in printer ink and 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, processing aids and solvents
- 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 care products
- Consumer use in other uses in cleaning and furniture care products, including wood cleaners and gasket removers
- Consumer use in other uses in lubricant and lubricant additives, including hydrophilic coatings

EPA has determined that the following conditions of use of NMP present an unreasonable risk of injury to health or the environment. EPA will initiate TSCA Section 6(a) risk management actions on these conditions of use as required under TSCA Section 6(c)(1). Pursuant to TSCA Section 6(i)(2), the unreasonable risk determinations for these conditions of use are not considered final agency action.

Manufacturing that Presents an Unreasonable Risk

- Domestic manufacture
- Import

Processing that Presents an Unreasonable Risk

- As a reactant or intermediate in plastic material and resin manufacturing and other non-incorporative processing
- 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 Uses that Present an Unreasonable Risk

- Consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants

Disposal that Presents an Unreasonable Risk

- Disposal