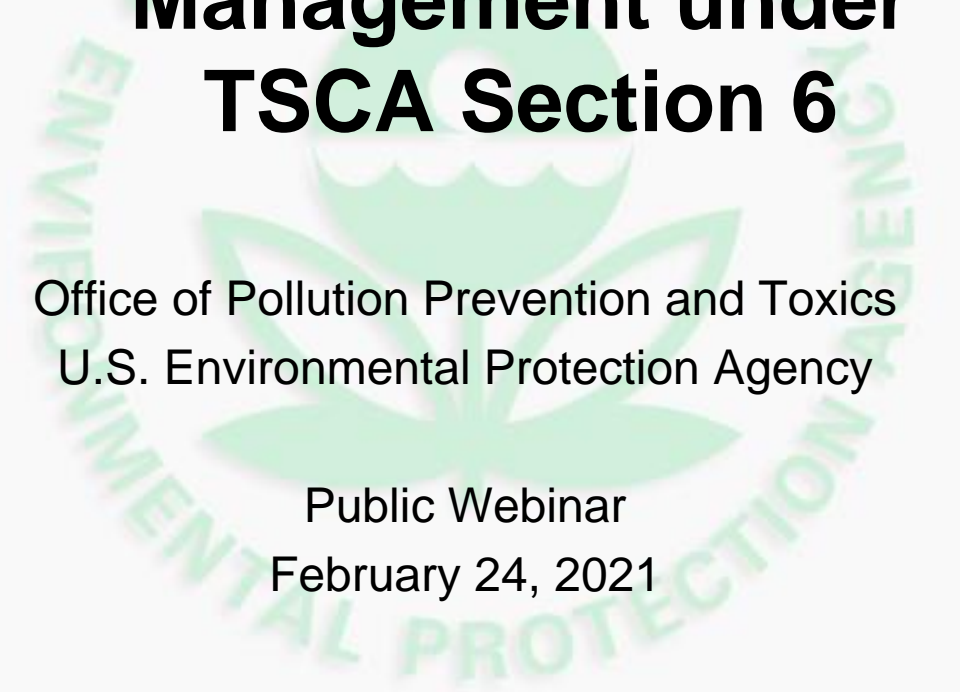


N-Methylpyrrolidone (NMP) Risk Evaluation and Risk Management under TSCA Section 6

Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Public Webinar
February 24, 2021





Agenda

- Background on Risk Evaluations
- Findings from Risk Evaluation for n-Methylpyrrolidone (NMP)
- Risk Management Requirements under TSCA
- Types of Information to Inform Risk Management
- Principles for Transparency During Risk Management
- Additional Information

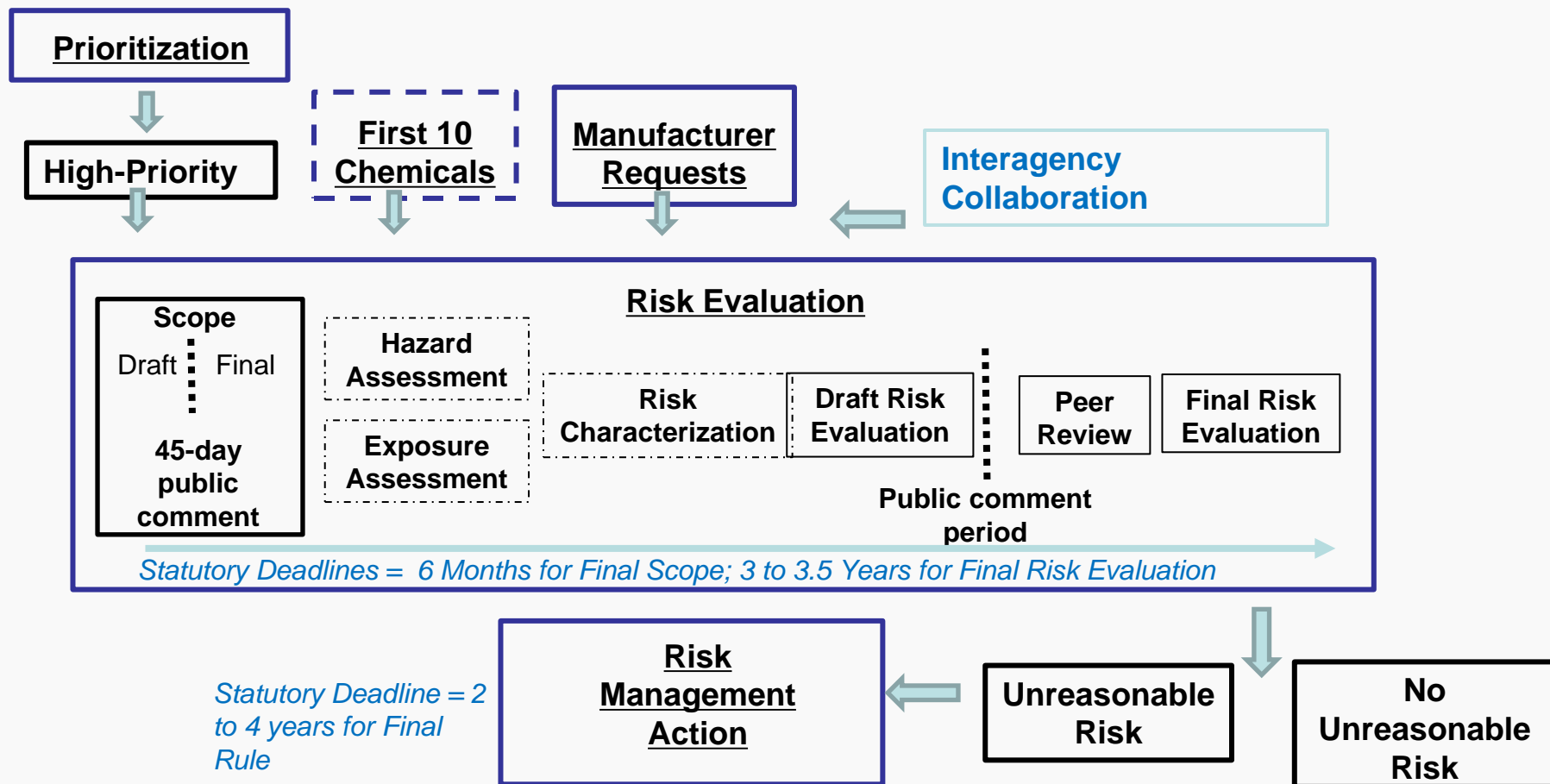


Risk Evaluation Statutory Requirements

- EPA must evaluate the risks presented by a chemical under the conditions of use and determine if the chemical presents an unreasonable risk of injury to health or the environment under the conditions of use
 - Without consideration of cost or other non-risk factors
 - Including unreasonable risk to potentially exposed or susceptible subpopulation(s) determined to be relevant to the evaluation
- TSCA requires a risk evaluation be completed within 3 – 3.5 years



Risk Evaluation Process and Timeline





Overview of Risk Evaluation for NMP

- Final risk evaluation published December 30, 2020
 - 37 conditions of use were evaluated
 - Final risk evaluation follows a series of risk evaluation activities
 - NMP draft risk evaluation: November 2019; NMP problem formulation: June 2018; NMP scope document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation
 - 35 public comments received on the draft risk evaluation (comment period closed January 21, 2020)
 - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (December 2019)
- 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

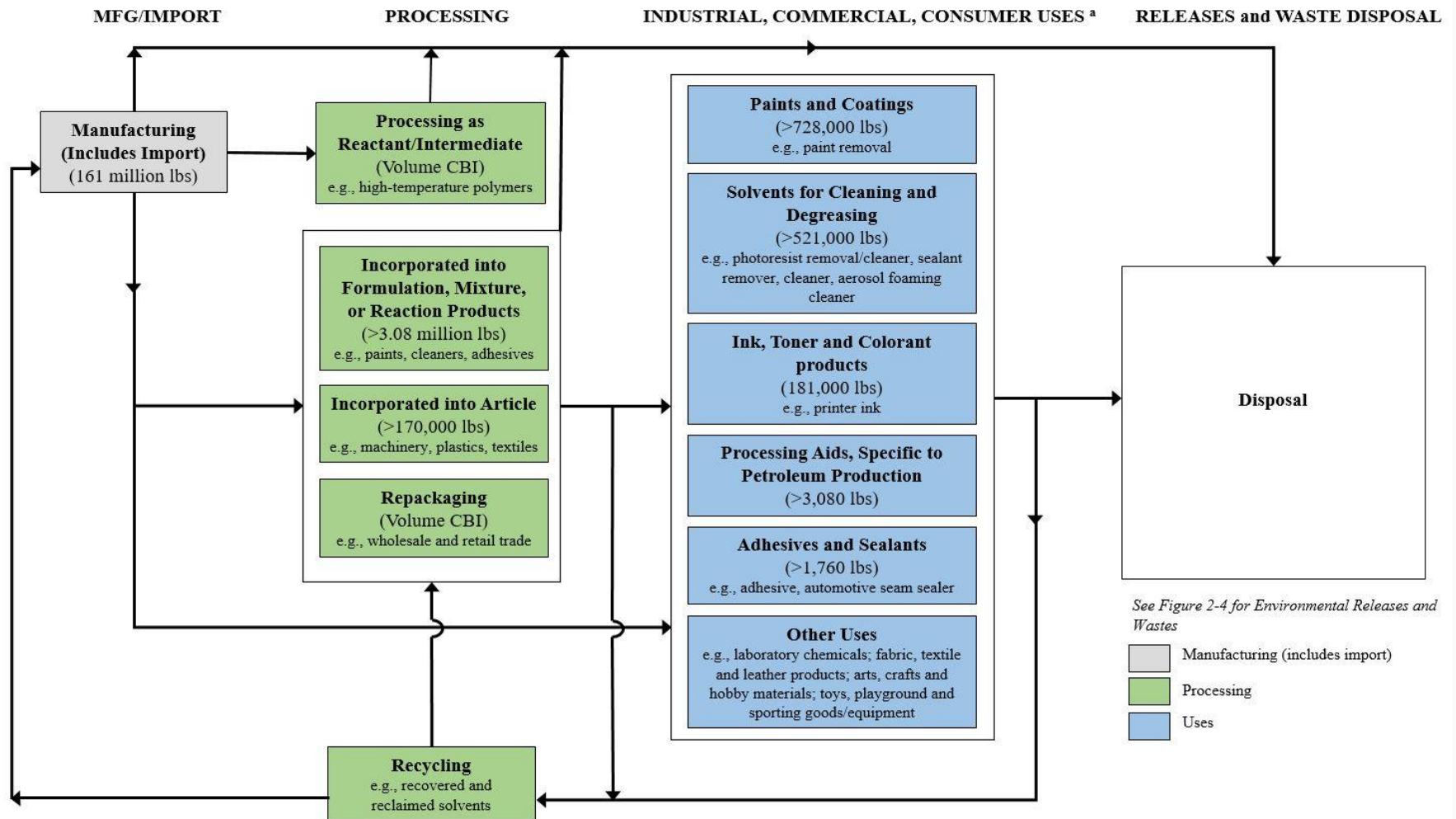


General Information on NMP

- NMP is a colorless liquid and a semi-volatile organic compound. It is both produced in and imported into the United States
- EPA identified conditions of use during various life cycle stages of NMP, such as manufacturing (including import), processing, distribution in commerce, use (industrial, commercial, and consumer), and disposal
- NMP has a wide range of uses, including production of paints and coatings, as a solvent for cleaning and degreasing, and in the manufacture of electronics
- A variety of consumer and commercial products use NMP, such as adhesives and sealants, as well as adhesive removers, automotive care products, and paints and coatings
- The total aggregate production volume was over 160 million pounds in 2015



NMP Life Cycle Diagram





Determinations of No Unreasonable Risk

- EPA determined that NMP does not present an unreasonable risk to the environment and general population under the conditions of use
- EPA determined that the following 11 of the 37 conditions of use of NMP do not present an unreasonable risk of injury to health or the environment:
 - Distribution in commerce
 - Industrial and commercial use in ink, toner and colorant products
 - Industrial and commercial use in soldering materials
 - Industrial and commercial use in fertilizer and other agricultural chemical manufacturing
 - Consumer use in paint and coating removers; in adhesive removers; in paints and coatings in lacquers, stains, varnishes, primers and floor finishes; in paint additives and coating additives not described by other codes in paints and arts and crafts paints; other uses in automotive care products; other uses in cleaning and furniture care products including wood cleaners and gasket removers; and in lubricants and lubricant additives including hydrophilic coatings
- These no unreasonable risk determinations are considered final agency actions and are issued by order pursuant to TSCA section 6(i)(1)



Unreasonable Risk Determinations

- EPA determined that 26 of the 37 conditions of use of NMP present an unreasonable risk of injury to health
- EPA's determinations are based on unreasonable risks of injury to:
 - Workers during occupational exposures
 - Consumers during exposures to one consumer use
- EPA's risk evaluation identified unreasonable risks for non-cancer developmental effects from acute inhalation and dermal exposures and reproductive effects from chronic inhalation and dermal exposures to NMP



Manufacturing and Processing Uses that Present an Unreasonable Risk

- Manufacturing (domestic manufacturing)
- Manufacturing (import)
- Processing: As a reactant/intermediate in plastic material and resin manufacturing and other non-incorporative processing
- Processing: Incorporation into formulation, mixture or reaction product in multiple industrial sectors
- Processing: Incorporation into articles in lubricants and lubricant additives in machinery manufacturing
- Processing: Incorporation into articles in paint additives and coating additives not described by other codes in transportation equipment manufacturing
- Processing: Incorporation into articles as a solvent (which becomes part of a product formulation or mixture) including in textiles, apparel and leather manufacturing
- Processing: Incorporation into articles in other sectors, including in plastic product manufacturing
- Processing: Repackaging in wholesale and retail trade
- Processing: 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, Commercial and Disposal Uses that Present an Unreasonable Risk, cont.

- 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
- Disposal



Consumer Use that Presents Unreasonable Risk

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



Basis for Unreasonable Risk Determination: Workers

- The unreasonable risk determinations for workers are based on the following health hazards during occupational exposures of NMP:
 - Developmental effects from acute inhalation and dermal exposures
 - Reproductive effects from chronic inhalation and dermal exposures
- Personal Protective Equipment (PPE):
 - There is no OSHA permissible exposure limit (PEL) for NMP. Many conditions of use presented an unreasonable risk to workers even with use of respirators with APF 10 and gloves with PF of 5 or 10
 - EPA does not assume occupational non-users use PPE because they do not handle the chemical



Basis for Unreasonable Risk Determination: Consumers

- The unreasonable risk determination for consumers is based on the following health hazards during consumer exposures to NMP:
 - Developmental toxicity from acute inhalation and dermal exposure
- EPA does not assume consumers use PPE
- The unreasonable risk determination was based on the high intensity use risk estimates for consumers
- EPA did not evaluate chronic exposures to NMP for consumers because EPA considered the frequency of consumer product use to be too low to create chronic risk concerns



Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- EPA must issue a TSCA section 6(a) rule following risk evaluation to address all identified unreasonable risks within two years:
 - Proposed rule one year after risk evaluation
 - Final rule two years after risk evaluation
- Specific requirements on consideration of alternatives, selecting among options and statement of effects apply to risk management rules
- Input from stakeholders is critical to the process



TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase



TSCA Section 6(a) Regulatory Options

- TSCA provides authority to regulate entities including:
 - Distributors
 - Manufacturers and processors (*e.g.*, formulators)
 - Commercial users (workplaces and workers)
 - Entities disposing of chemicals for commercial purposes
- Cannot directly regulate consumer users
 - Under TSCA, EPA has authority to regulate at the manufacturing, processing, and distribution level in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use
 - These authorities allow EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers



TSCA Section 6(c)

In promulgating any rule under TSCA section 6(a), EPA must consider and publish a statement of effects of the rule based on reasonably available information with respect to:

- The effects and magnitude of exposure to human health
- The effects and magnitude of exposure to environment
- The benefits of the chemical for various uses
- The reasonably ascertainable economic consequences of the rule, including consideration of:
 - The likely effect on the national economy, small business, technological innovation, the environment, and public health
 - The costs and benefits of the proposed and final regulatory action and one or more primary regulatory alternatives
 - The cost effectiveness of the proposed regulatory action and 1 or more primary regulatory alternatives



Executive Orders Relevant to 6(a) Rulemakings

- EO 12866: Regulatory Planning and Review
- EO 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
- EO 13045: Protection of Children from Environmental Health & Safety Risks
- EO 13132: Federalism
- EO 13175: Consultation and Coordination with Indian Tribal Governments
- EO 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
- EO 13272: Proper Consideration of Small Entities in Agency Rulemaking



Types of Information to Inform Risk Management

- Suggestions on effective methods EPA can use to address the unreasonable risks
- Input on protective regulatory approaches
- Information related to controlling exposures, including current work practices, engineering, and administrative controls
- Information on essential uses, and the impacts if the chemical were not available
- Identification of uses that have been phased out, or can be phased out, and thus are no longer needed
- Any information on substitute chemicals that are safe and effective alternatives
- Suggestions on how EPA can further improve its regulatory processes or be more transparent



Principles for Transparency During Risk Management

- Transparent, proactive, and meaningful engagement
- One-on-one meetings, public webinars, and required consultations with state and local governments, Tribes, environmental justice communities, and small businesses
- Extensive dialogue will help people understand the findings in the risk evaluations, the risk management process required by TSCA, and the options available for managing unreasonable risks
- Seeking input from stakeholders on potential risk management approaches, their effectiveness, and impacts those approaches might have on businesses, workers, and consumers
- Input can help the agency develop regulations that are practical and protective



Coordination and Engagement

- In developing risk management approaches EPA:
 - Consults with stakeholders to learn about conditions of use, existing engineering controls, personal protection equipment (PPE), available alternatives, or other programs to tailor effective risk management solutions
 - Conducts site visits as necessary to obtain detailed information on existing practices in chemical manufacturing, processing, and use
 - Develops an extensive network among stakeholders to ensure regulatory approaches are fully informed and based on current conditions



Opportunities for Engagement

- One-on-one meetings
- Webinars providing overviews of final risk evaluations and unreasonable risk determinations
- Consultations seeking targeted feedback, with:
 - States and local governments
 - Tribes
 - Small businesses
 - Environmental justice organizations and communities



Additional Information

- General TSCA: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>
- Current Chemical Risk Management Activities: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities>
- NMP Risk Management: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-n-methylpyrrolidone-nmp>
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