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United States
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Problem Formulation of the Risk Evaluation for N-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-)

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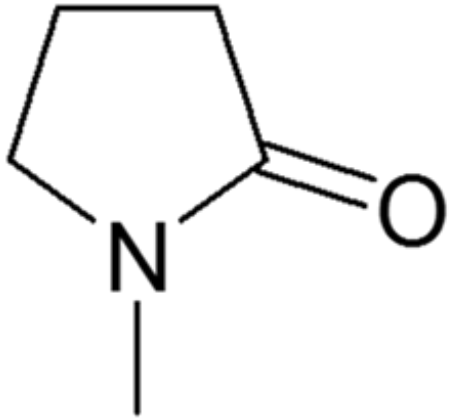

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ABBREVIATIONS

°C	Degrees Celsius
AIHA	American Industrial Hygiene Association
atm	Atmosphere(s)
ATSDR	Agency for Toxic Substances and Disease Registry
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CCL	Contaminant Candidate List
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CEM	Consumer Exposure Model
CFR	Code of Federal Regulations
ChV	Chronic Value
cm^3	Cubic Centimeter(s)
COC	Concentration of Concern
CSCL	Chemical Substances Control Law
DMR	Discharge Monitoring Report
DTSC	Department of Toxic Substances Control
EC	European Commission
EC_{50}	Effective Concentration with 50% immobilized test organisms
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ESD	Emission Scenario Document
EU	European Union
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetic Act
GBL	Gamma-Butyrolactone
GS	Generic Scenarios
HESIS	Hazard Evaluation System and Information Service
HHE	Health Hazard Evaluation
HPV	High Production Volume
Hr	Hour
IMAP	Inventory Multi-Tiered Assessment and Prioritisation
IRIS	Integrated Risk Information System
kg	Kilogram(s)
L	Liter(s)
LOAEL	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effect Concentration
lb	Pound(s)
LC50	Lethal Concentration of 50% test organisms
LOEC	Lowest Observed Effect Concentration
Log K_{oc}	Logarithmic Soil Organic Carbon:Water Partition Coefficient
Log K_{ow}	Logarithmic Octanol:Water Partition Coefficient
m^3	Cubic Meter(s)
MADL	Maximum Allowable Dose Level

mg	Milligram(s)
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
ONU	Occupational Non-User
µg	Microgram(s)
MMA	Monomethylamine
mmHg	Millimeter(s) of Mercury
mPa·s	Millipascal(s)-Second
MITI	Ministry of International Trade and Industry
SDS	Safety Data Sheet
MSW	Municipal Solid Waste
NAICS	North American Industry Classification System
NESHAP	National Emission Standards for Hazardous Air Pollutants
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NIOSH	National Institute for Occupational Safety and Health
NITE	National Institute of Technology and Evaluation
NMP	N-Methylpyrrolidone
NSPS	New Source Performance Standards
NWQMC	National Water Quality Monitoring Council
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Cooperation and Development
OEHHA	Office of Environmental Health Hazard Assessment
OEL	Occupational Exposure Limits
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PBZ	Personal Breathing Zone
PDE	Permissible Daily Exposure
PDM	Probabilistic Dilution Model
PECO	Populations, Exposures, Comparisons, Outcomes
PEL	Permissible Exposure Limit
POD	Point of Departure
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
ppm	Part(s) per Million
PSD	Particle Size Distribution
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SDWA	Safe Drinking Water Act
SIDS	Screening Information Data Set
SNAP	Significant New Alternatives Policy
STORET	STOrage and RETrieval
SVHC	Substance of Very High Concern
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TWA	Time-Weighted Average
USGS	United States Geological Survey
VOC	Volatile Organic Compound
WEEL	Workplace Environmental Exposure Level
Yr	Years(s)

EXECUTIVE SUMMARY

TSCA § 6(b)(4) requires the U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use." In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). N-methylpyrrolidone (NMP) was one of these chemicals.

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. In June 2017, EPA published the Scope of the Risk Evaluation for NMP (EPA-HQ-OPPT-2016-0743) As explained in the scope document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on the problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for NMP. Comments received on this problem formulation document will inform development of the draft risk evaluation.

This problem formulation document refines the conditions of use and exposures presented in the scope of the risk evaluation for NMP and presents refinements to the conceptual models and analysis plan that describe how EPA expects to evaluate risks.

N-methylpyrrolidone, also called N-methyl-2-pyrrolidone, or 1-methyl-2-pyrrolidone, is a high production volume (HPV) chemical that is widely used during the manufacture and production of polymers, pharmaceuticals, agrichemicals and petroleum products (U.S. EPA, 2015). For the purposes of this problem formulation, "NMP" refers to N-methylpyrrolidone (CASRN 872-50-4). NMP is subject to federal and state regulations and reporting requirements. In terms of federal regulation, NMP has been a reportable Toxics Release Inventory (TRI) chemical under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) since 1995. NMP is also reported under the Toxic Substances Control Act's Chemical Data Reporting (CDR) Rule. NMP is subject to Clean Air Act (CAA) Section 111 Performance Standards for New Stationary Sources of Air Pollution for volatile organic carbon (VOC) emissions from synthetic organic chemical manufacturing industry distillation operations and reactor processes. NMP also is listed under the CAA's National Volatile Organic Compound Emission Standards for Aerosol Coatings. NMP is identified on both the Third (2009) and Fourth (2016) Contaminant Candidate Lists under the Safe Drinking Water Act (SDWA).

Information on domestic manufacture, processing and use of NMP is available to EPA through its Chemical Data Reporting (CDR) Rule, issued under TSCA. In 2015, more than 160 million pounds of NMP was reported to be manufactured (including imported) in the U.S. According to a recent EPA market report, the primary uses for NMP include petrochemical processing, engineering plastic coatings, electronics, pharmaceutical and agrichemical manufacturing and solvent cleaning (EPA-HQ-OPPT-2016-0743).

This document presents the potential exposures that may result from NMP conditions of use considered under the scope of the risk evaluation. Exposures may occur to workers and occupational non-users (i.e., workers who do not directly handle NMP but perform work in an area where it is used), consumers and bystanders (i.e., non-users who are incidentally exposed to NMP as a result of consumer product use)

and members of the general population. Workers and occupational non-users may be exposed to NMP during various conditions of use (e.g., manufacturing, processing and industrial/commercial uses). General population exposures may result from industrial and/or commercial uses; industrial releases to air, water or land and other conditions of use. EPA expects the highest exposures to NMP will generally involve workers in industrial and commercial settings; however, NMP occurs in numerous consumer products and can therefore, result in exposures outside the occupational setting. For NMP, EPA considers workers, occupational non-users, consumers, bystanders, and certain other groups of individuals who may experience greater exposures than the general population to be potentially exposed or susceptible subpopulations. During risk evaluation, EPA expects to further analyze inhalation exposures to NMP vapor and mist (for workers, occupational non-users, consumers and bystanders). EPA also expects to analyze dermal exposures from direct contact with NMP-containing liquids (for workers and consumers) and indirect exposure from vapor-through-skin contact (for workers, occupational non-users, consumers and bystanders).

NMP has been the subject of numerous assessments with various hazards identified following oral, dermal and inhalation exposure. Reproductive/developmental effects were identified as sensitive endpoints for evaluating human health risks in the previous assessment of NMP use in paint and coating removal (U.S. EPA, 2015). EPA expects to evaluate all potential hazards for NMP, using the previous analysis as a starting point for identifying key and supporting studies and including any information found in recent literature. The relevant studies will be evaluated using the data quality criteria provided in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018). Previously identified human health hazards include irritation and adverse effects on hepatic, renal, immune, reproductive/developmental and central nervous systems. If additional hazard concerns are identified during systematic review of the literature, these effects will also be considered. Risks will be evaluated based on the specific hazards and exposure scenarios identified.

The revised conceptual models presented in this problem formulation identify conditions of use; exposure pathways (e.g., media); exposure routes (e.g., inhalation, dermal, oral); potentially exposed or susceptible subpopulations; and hazards EPA expects to consider during risk evaluation. The initial conceptual models provided in the scope document were revised during problem formulation based on evaluation of reasonably available information for physical and chemical properties, fate, exposures, hazards, and conditions of use and based upon consideration of other statutory and regulatory authorities. In each problem formulation document for the first 10 chemical substances, EPA also refined the activities, hazards, and exposure pathways that will be included in and excluded from the risk evaluation.

EPA's overall objectives are to conduct timely, relevant, high-quality and scientifically credible risk evaluations within the statutory deadlines and to evaluate the conditions of use that raise the greatest potential for risk 82 FR 33726, 33728 (July 20, 2017).

1 INTRODUCTION

This document presents for comment the problem formulation of the risk evaluation to be conducted for NMP under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act (TSCA), the Nation's primary chemicals management law, on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). These 10 chemical substances were drawn from the 2014 update of EPA's TSCA Work Plan for Chemical Assessments, a list of chemicals that EPA identified in 2012 and updated in 2014 (currently totaling 90 chemicals) for further assessment under TSCA. EPA's designation of the first 10 chemical substances constituted the initiation of the risk evaluation process for each of these chemical substances, pursuant to the requirements of TSCA § 6(b)(4).

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider, within 6 months after the initiation of a risk evaluation. The scope documents for all first 10 chemical substances were issued on June 22, 2017. The first 10 problem formulation documents are a refinement of what was presented in the first 10 scope documents. TSCA § 6(b)(4)(D) does not distinguish between scoping and problem formulation, and requires EPA to issue scope documents that include information about the chemical substance, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that the Administrator expects to consider in the risk evaluation. In the future, EPA expects scoping and problem formulation to be completed prior to the issuance of scope documents and intends to issue scope documents that include problem formulation.

As explained in the scope document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for NMP. Comments received on this problem formulation document will inform development of the draft risk evaluation.

The Agency defines problem formulation as the analytical phase of the risk assessment in which "the purpose for the assessment is articulated, the problem is defined and a plan for analyzing and characterizing risk is determined" [see Section 2.2 of the *Framework for Human Health Risk Assessment to Inform Decision Making*; (U.S. EPA, 2014)]. The outcome of problem formulation includes the conceptual model(s) and an analysis plan. The conceptual model describes the linkages between stressors and adverse human health effects, including the stressor(s), exposure pathway(s), exposed life stage(s) and population(s) and endpoint(s) that will be addressed during risk evaluation (U.S. EPA, 2014). The analysis plan follows the development of the conceptual model(s) and is intended to describe the approach for conducting the risk evaluation, including its design, methods, key inputs and intended outputs as described in EPA's *Human Health Risk Assessment Fram*ework (U.S. EPA, 2014). The problem formulation documents refine the initial conceptual models and analysis plans that were provided in the scope documents.

EPA identified exposure pathways that are covered under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes –

namely, the Safe Drinking Water Act (SDWA), and the Resource Conservation and Recovery Act (RCRA) – which EPA does not expect to include in the risk evaluation. As a general matter, EPA believes certain programs under other Federal environmental laws adequately assess and effectively manage the risks for those covered exposure pathways. To use Agency resources efficiently under the TSCA program, to avoid duplicating efforts taken pursuant to other Agency programs, to maximize scientific and analytical efforts and to meet the three-year statutory deadline, EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes.[1] EPA does not expect to include any such excluded pathways in the risk evaluation. The provisions of various EPA environmental statutes and their implementing regulations represent the judgement of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under various environmental statutes.

EPA also identified any conditions of use, hazards, or exposure pathways which were included in the scope document and that EPA expects to include in the risk evaluation but which EPA does not expect to further analyze during risk evaluation. EPA expects to be able to reach conclusions about specific conditions of use, hazards or exposure pathways without further analysis and therefore expects to conduct no further analysis on those conditions of use, hazards or exposure pathways in order to focus the Agency's resources on more extensive or quantitative analyses. Each risk evaluation will be "fit-for-purpose," meaning not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without comprehensive or quantitative risk evaluations. 82 FR 33726, 33734, 33739 (July 20, 2017).

EPA received comments on the published scope document for NMP and has considered the comments specific to NMP in this problem formulation document. EPA is soliciting public comment on this problem formulation document and when the draft risk evaluation is issued, the Agency intends to respond to comments that are submitted. In its draft risk evaluation, EPA may revise the conclusions and approaches contained in this problem formulation, including the conditions of use and pathways covered and the conceptual models and analysis plan, based on comments received.

1.1 Regulatory History

EPA conducted a search of existing laws and regulations and assessments pertaining to NMP. EPA compiled information available from federal, state, international and other government sources, as cited in Appendix A. EPA evaluated and considered the impact of existing laws and regulations (e.g., regulations on landfill disposal, design, and operations) during problem formulation to determine what, if any further analysis might be necessary as part of the risk evaluation. Additional consideration of the nexus between these existing regulations and TSCA conditions of use may be necessary as specific exposure scenarios are developed during the analysis phase of the risk evaluation.

Federal Laws and Regulations

NMP is subject to federal statutes or regulations other than TSCA, that are implemented by other offices within EPA and/or other federal agencies/departments. A summary of federal laws, regulations and implementing authorities is provided in Appendix A.1.

[1] As explained in the final rule for chemical risk evaluation procedures, "EPA may, on a case-by case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination." 82 FR 33726, 33728 (July 20, 2017).

State Laws and Regulations
NMP is subject to state statutes or regulations implemented by state agencies or departments. A summary of state laws, regulations and implementing authorities is provided in Appendix A.2.

Laws and Regulations in Other Countries and International Treaties or Agreements
NMP is subject to statutes or regulations in countries other than the United States and/or international treaties and/or agreements. A summary of these laws, regulations, treaties and/or agreements is provided in Appendix A.3.

1.2 Assessment History

EPA has identified assessments conducted by other EPA Programs and other organizations (see Table 1-1). Depending on the source, these assessments may include information on conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations. Table 1-1 shows the assessments that have been conducted. EPA found no additional assessments beyond those listed.

In addition to using this information, EPA intends to conduct a full review of the relevant data/information collected in the initial comprehensive search [see *NMP (CASRN 872-50-4) Bibliography: Supplemental File for the TSCA Scope Document*, (EPA-HQ-OPPT-2016-0743)] following the literature search and screening strategies documented in the *Strategy for Conducting Literature Searches for NMP: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0743). This will ensure that EPA considers all data/information that has been made available since these assessments were conducted.

Table 1-1. Assessment History of NMP

Authoring Organization	Assessment
EPA Assessments	
U.S. EPA, Office of Pollution Prevention and Toxics (OPPT)	TSCA Work Plan Chemical Risk Assessment N-Methylpyrrolidone: Paint Stripping Use CASRN 872-50-4 U.S. EPA (2015)
U.S. EPA, OPPT	Re-assessment of Pesticide Inert Ingredient Exemption under the Food Quality Protection Act U.S. EPA (2006a)
Other U.S.-Based Organizations	
California Office of Environmental Health Hazard Assessment (OEHHA)	Proposition 65 Maximum Allowable Dose Level for Reproductive Toxicity OEHHA (2003)
International	
National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Australian Government	Human Health Tier III assessment NICNAS (2013)
Government of Canada, Environment Canada, Health Canada	Draft Screening Assessment of Risks to Human and Ecological Receptors EC/HC (2017)
European Commission (EC), Scientific Committee on Occupational Exposure Limits (OELs)	Evaluation of Occupational Exposure Limits for NMP EC (2016)

Authoring Organization	Assessment
Organisation for Economic Co-operation and Development (OECD), Cooperative Chemicals Assessment Program	NMP: SIDS Initial Assessment Profile OECD (2007)
World Health Organization (WHO) International Programme on Chemical Safety (IPCS)	Concise International Chemical Assessment Document 35 N-METHYLPYRROLIDONE WHO (2001)
Danish Ministry of the Environment Environmental Protection Agency	Survey of NMP - Miljøstyrelsen (Danish EPA, 2015)

1.3 Data and Information Collection

EPA/OPPT generally applies a systematic review process and workflow that includes: (1) data collection; (2) data evaluation; and (3) integration of the scientific data used in risk evaluations developed under TSCA. Scientific analysis is often iterative in nature as new knowledge is obtained. Hence, EPA/OPPT expects multiple refinements regarding data collection will occur during the process of risk evaluation. Additional information that may be considered, and was not part of the initial comprehensive bibliographies will be documented in the Draft Risk Evaluation for NMP.

Data Collection: Data Search

EPA/OPPT conducted chemical-specific searches for information on: physical-chemical properties; environmental fate and transport; conditions of use; environmental and human exposures; and ecological and human health hazards, including potentially exposed or susceptible subpopulations.

EPA/OPPT designed its initial data search to be broad enough to capture a comprehensive set of sources containing data and/or information potentially relevant to the risk evaluation. For most disciplines, the search was not limited by date and was conducted on a wide range of data sources, including but not limited to: peer-reviewed and gray literature (e.g., publicly-available industry reports, trade association resources, government reports). When available, EPA/OPPT relied on the search strategies from recent assessments to identify relevant references and supplemented these searches to identify relevant information published after the end date of the previous search to capture more recent literature. *Strategy for Conducting Literature Searches for NMP: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0743) provides details about the data sources and search terms used in the literature search.

Data Collection: Data Screening

Following the data search, references were screened and categorized using selection criteria outlined in the *Strategy for Conducting Literature Searches for NMP: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0743). Titles and abstracts were screened against the criteria as a first step with the goal of identifying a smaller subset of the relevant data to move forward into the subsequent data extraction and data evaluation steps. Prior to full-text review, EPA/OPPT anticipates refinements to the screening strategies, as informed by an evaluation of the performance of the initial title/abstract screening and categorization process.

The categorization scheme (or tagging structure) used for data screening varies by scientific discipline (i.e., physical-chemical properties; environmental fate and transport; chemical use/conditions of use information; environmental and human exposures, including potentially exposed or susceptible

subpopulations identified by virtue of greater exposure; human health hazards, including potentially exposed or susceptible subpopulations identified by virtue of greater susceptibility; and ecological hazards). However, within each data set, there are two broad categories or data tags: (1) *on-topic* references or (2) *off-topic* references. *On-topic* references are those that may contain data and/or information relevant to the risk evaluation. *Off-topic* references are those that do not appear to contain data or information relevant to the risk evaluation. The *Strategy for Conducting Literature Searches for NMP: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0743) discusses the inclusion and exclusion criteria that EPA/OPPT used to categorize references as *on-topic* or *off-topic*.

Additional data screening using sub-categories (or sub-tags) was also performed to facilitate further sorting of data/information. For example, identifying references by source type (e.g., published peer-reviewed journal article, government report); data type (e.g., primary data, review article); human health hazard (e.g., liver toxicity, reproductive toxicity); or chemical-specific and use-specific data or information. These sub-categories are described in the *Strategy for Conducting Literature Searches for NMP: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0743) and will be used to organize the different streams of data during the stages of data evaluation and data integration steps of systematic review.

Results of the initial search and categorization results can be found in the *NMP (CASRN 872-50-4) Bibliography: Supplemental File for the TSCA Scope Document*, (EPA-HQ-OPPT-2016-0743). This document provides a comprehensive list (bibliography) of the sources of data identified by the initial search and categorization for *on-topic* and *off-topic* references. Because systematic review is an iterative process, EPA/OPPT expects that some references may move from *on-topic* to *off-topic* categories, and vice versa. Moreover, targeted supplemental searches may also be conducted to address specific needs for the analysis phase (e.g., to locate specific data needed for modeling); hence, additional *on-topic* references not initially identified in the initial search may be identified as the systematic review process proceeds.

1.4 Data Screening During Problem Formulation

EPA/OPPT is in the process of completing the full text screening of the on-topic references identified in the *NMP (CASRN 872-50-4) Bibliography: Supplemental File for the TSCA Scope Document*, (EPA-HQ-OPPT-2016-0743). The screening process and criteria at the full-text level is described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018). Appendix G provides the inclusion and exclusion criteria applied at the full text screening. The eligibility criteria are guided by the analytical considerations in the revised conceptual models and analysis plan, as discussed in the problem formulation document. Thus, it is expected that the number of data/information sources entering evaluation is reduced to those that are relevant to address the technical approach and issues described in the analysis plan of this document.

Following the screening process, the quality of the included data/information sources will be assessed using the evaluation strategies described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

2 PROBLEM FORMULATION

As required by TSCA, the scope of the risk evaluation identifies the conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations the Administrator expects to consider. To communicate and visually convey the relationships between these components, EPA included in the scope document a life cycle diagram and conceptual models that describe the potential relationships between NMP and human and ecological receptors. During problem formulation, EPA revised the conceptual models based on further data gathering and analysis as presented in this document. An updated analysis plan is also included which identifies, to the extent feasible, the approaches and methods that EPA may use to assess exposures, effects (hazards) and risks associated with the conditions of use identified for NMP.

2.1 Physical-Chemical Properties

Physical-chemical properties influence the environmental behavior and the toxic properties of a chemical, thereby informing the potential conditions of use, exposure pathways, routes and hazards that EPA intends to consider. During problem formulation, EPA considered the measured or estimated physical-chemical properties set forth in Table 2-1. The value reported for vapor pressure was updated (0.345 mmHg) to reflect information obtained from a primary source, which is considered more defensible than the original value (0.19 mmHg) taken from a secondary source.

Table 2-1. Physical-Chemical Properties of NMP

Property	Value [a]	Reference
Molecular formula	C_5H_9ON	
Molecular weight	99.1 g/mole	O'Neil et al. (2006)
Physical form	Colorless to yellow liquid; amine odor	O'Neil et al. (2006)
Melting point	-25°C	Ashford (1994)
Boiling point	202°C	O'Neil et al. (2006)
Density	1.03 at 25°C	O'Neil et al. (2006)
Vapor pressure	0.345 mmHg at 25°C	Daubert and Danner (1989)
Vapor density	3.4 (air = 1)	NFPA (1997)
Water solubility	1,000 g/L at 25°C	O'Neil et al. (2006)
Octanol:water partition coefficient (log K_{ow})	- 0.38 at 25°C	Sasaki et al. (1988)
Henry's Law constant	3.2×10^{-9} atm m^3/mole	U.S. EPA (2012b)
Flash point	95°C (open cup)	Riddick et al. (1986)
Autoflammability	Not available	
Viscosity	1.65 mPa·s at 25°C	O'Neil et al. (2006)
Refractive index	Not applicable	
Dielectric constant	Not applicable	

[a] Measured unless otherwise noted.

2.2 Conditions of Use

TSCA § 3(4) defines the conditions of use as ‘‘the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.’’

2.2.1 Data and Information Sources

In the scope documents, EPA identified, based on reasonably available information, the conditions of use for the subject chemicals. EPA searched available data sources (e.g., *Use and Market Profile for NMP*, EPA-HQ-OPPT-2016-0743). Based on this search, EPA published a preliminary list of information and sources related to chemical conditions of use (see *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: NMP*, EPA-HQ-OPPT-2016-0743-0003) prior to a February 2017 public meeting on scoping efforts convened to solicit comment and input from the public. EPA also convened meetings with companies, industry groups, chemical users and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. The information and input received from the public and stakeholder meetings was incorporated into this problem formulation document to the extent appropriate, as indicated in Table 2-3. Thus, EPA believes the identified manufacturing, processing, distribution, use and disposal activities constitute the intended, known, and reasonably foreseen activities associated with the subject chemical, based on reasonably available information.

2.2.2 Identification of Conditions of Use

To determine the current conditions of use of NMP and conversely, activities that do not qualify as conditions of use, EPA conducted extensive research and outreach. This included EPA’s review of published literature and online databases including the most recent data available from EPA’s Chemical Data Reporting program (CDR) and Safety Data Sheets (SDSs). EPA also conducted online research by reviewing company websites of potential manufacturers, importers, distributors, retailers, or other users of NMP and queried government and commercial trade databases. EPA also received comments on the *Scope of the Risk Evaluation for NMP* (EPA-HQ-OPPT-2016-0743) that were used to determine the conditions of use. In addition, EPA convened meetings with companies, industry groups, chemical users, states, environmental groups, and other stakeholders to aid in identifying and verifying the conditions of use identified by EPA. Those meetings included a February 14, 2017 public meeting with such entities (EPA-HQ-OPPT-2016-0743).

EPA has removed from the problem formulation any conditions of use that EPA does not plan to include in the risk evaluation – for example because EPA has insufficient information to find certain activities are circumstances under which the chemical is actually “intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of.” EPA has also identified any conditions of use that EPA does not expect to include in the risk evaluation. As explained in the final rule for Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, TSCA section 6(b)(4)(D) requires EPA to identify "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that the Administrator expects to consider” in a risk evaluation, suggesting that EPA may exclude specific activities that EPA has determined to be conditions of use on a case-by-case basis. (82 FR 33736, 33729; July 20, 2017). For example, EPA may exclude conditions of use that the Agency has sufficient basis to conclude would present only *de minimis* exposures or otherwise insignificant risks (such as use in a closed system that effectively precludes exposure, or use as an intermediate).

The activities that EPA no longer believes are conditions of use or that were otherwise excluded during problem formulation are described in Section 2.2.2.1. The conditions of use included in the scope of the risk evaluation are summarized in Section 2.2.2.2

2.2.2.1 Categories and Subcategories Determined Not to be Conditions of Use or Otherwise Excluded During Problem Formulation

Based on the foregoing research and outreach, EPA does not have reason to believe that any conditions of use identified in the NMP Scope document should be excluded from the risk evaluation.

Table 2-2. Categories and Subcategories Determined Not to be Conditions of Use or Otherwise Excluded During Problem Formulation

Life Cycle Stage	Category [a]	Subcategory [b]	References
No activities were excluded from risk evaluation.			

2.2.2.2 Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

For NMP, EPA has conducted public outreach and literature searches to collect information about NMP's conditions of use and has reviewed reasonably available information obtained by EPA concerning activities associated with NMP. Based on this research and outreach, EPA does not have reason to believe that any conditions of use identified in the NMP scope should be excluded from risk evaluation. Therefore, all NMP conditions of use will be included in the risk evaluation.

NMP is widely used in the manufacture and production of electronics, petroleum products, pharmaceuticals, polymers and other specialty chemicals. It also has numerous applications in paints, coatings, and adhesives as well as products that facilitate their removal.

Table 2-3 summarizes each life cycle stage and the corresponding categories and subcategories of conditions of use for NMP that EPA expects to consider during risk evaluation. Using the 2016 CDR (U.S. EPA, 2016b), EPA identified industrial processing or use activities, industrial function categories and commercial and consumer use product categories. EPA identified the subcategories by supplementing CDR data with other published literature and information obtained through stakeholder consultations. For risk evaluations, EPA intends to consider each life cycle stage (with corresponding use categories and subcategories) and assess the potential sources of release and related exposures associated with that life cycle stage.

Beyond the uses identified in the *Scope of the Risk Evaluation for NMP* (EPA-HQ-OPPT-2016-0743), EPA has received no additional information identifying additional current conditions of use for NMP from public comment and stakeholder meetings.

Table 2-3. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Life Cycle Stage	Category [a]	Subcategory [b]	References
Manufacture	Domestic Manufacture	Domestic Manufacture	U.S. EPA (2016b)

Life Cycle Stage	Category [a]	Subcategory [b]	References
	Import	Import	U.S. EPA (2016b)
Processing	Processing as a reactant or intermediate	Intermediate in Plastic Material and Resin Manufacturing and in Pharmaceutical and Medicine Manufacturing	U.S. EPA (2016b), Public comments EPA-HQ-OPPT-2016-0743-0010, EPA-HQ-OPPT-2016-0743-0015, EPA-HQ-OPPT-2016-0743-0017
		Other	U.S. EPA (2016b)
	Incorporated into formulation, mixture or reaction product	Adhesives and sealant chemicals in Adhesive Manufacturing	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743, Public comments EPA-HQ-OPPT-2016-0743-0007, EPA-HQ-OPPT-2016-0743-0009, EPA-HQ-OPPT-2016-0743-0011
		Anti-adhesive agents in Printing and Related Support Activities	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743
		Paint additives and coating additives not described by other codes in Paint and Coating Manufacturing; and Print Ink Manufacturing	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743, Public comments EPA-HQ-OPPT-2016-0743-0007, EPA-HQ-OPPT-2016-0743-0009, EPA-HQ-OPPT-2016-0743-0013
		Plating agents and surface treating agents in Fabricated Metal Product Manufacturing	U.S. EPA (2016b)
Processing	Incorporated into formulation, mixture or reaction product	Processing aids, not otherwise listed in Plastic Material and Resin Manufacturing	U.S. EPA (2016b), Public comments EPA-HQ-OPPT-2016-0743-0015, EPA-HQ-OPPT-2016-0743-0017, EPA-HQ-OPPT-2016-0743-0035, EPA-HQ-OPPT-2016-0743-0038

Life Cycle Stage	Category [a]	Subcategory [b]	References
		Solvents (for cleaning or degreasing) in Non-Metallic Mineral Product Manufacturing; Machinery Manufacturing; Plastic Material and Resin Manufacturing; Primary Metal Manufacturing; Soap, Cleaning Compound and Toilet Preparation Manufacturing; Transportation Equipment Manufacturing; All Other Chemical Product and Preparation Manufacturing; Printing and Related Support Activities; Services; Wholesale and Retail Trade	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743, Public comments EPA-HQ-OPPT-2016-0743-0010, EPA-HQ-OPPT-2016-0743-0011, EPA-HQ-OPPT-2016-0743-0027, EPA-HQ-OPPT-2016-0743-0028
		Solvents (which become part of product formulation or mixture) in Electrical Equipment, Appliance and Component Manufacturing; Other Manufacturing; Paint and Coating Manufacturing; Print Ink Manufacturing; Soap, Cleaning Compound and Toilet Preparation Manufacturing; Transportation Equipment Manufacturing; All Other Chemical Product and Preparation Manufacturing; Printing and Related Support Activities; Wholesale and Retail Trade	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743, Public comments EPA-HQ-OPPT-2016-0743-0007, EPA-HQ-OPPT-2016-0743-0009, EPA-HQ-OPPT-2016-0743-0010, EPA-HQ-OPPT-2016-0743-0011, EPA-HQ-OPPT-2016-0743-0019, EPA-HQ-OPPT-2016-0743-0024, EPA-HQ-OPPT-2016-0743-0031, EPA-HQ-OPPT-2016-0743-0034
Processing	Incorporated into formulation, mixture or reaction product	Surface active agents in Soap, Cleaning Compound and Toilet Preparation Manufacturing	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743
		Other uses in Oil and Gas Drilling, Extraction and Support Activities; Plastic Material and Resin Manufacturing; Services	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743, Public comment EPA-HQ-OPPT-2016-0743-0016

Life Cycle Stage	Category [a]	Subcategory [b]	References
	Incorporated into article	Lubricants and lubricant additives in Machinery Manufacturing	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743
		Paint additives and coating additives not described by other codes in Transportation Equipment Manufacturing	U.S. EPA (2016b)
		Solvents (which become part of product formulation or mixture), including in Textiles, Apparel and Leather Manufacturing	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743, Public comment EPA-HQ-OPPT-2016-0743-0027
		Other, including in Plastic Product Manufacturing	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743; EPA-HQ-OPPT-2016-0743-0067
	Repackaging	Wholesale and Retail Trade	U.S. EPA (2016b)
	Recycling	Recycling	U.S. EPA (2017b), U.S. EPA (2016b), Public comments EPA-HQ-OPPT-2016-0743-0017, EPA-HQ-OPPT-2016-0743-0031
Distribution in commerce	Distribution	Distribution in Commerce	U.S. EPA (2017b), U.S. EPA (2016b); Use document EPA-HQ-OPPT-2016-0743-0003
Industrial commercial and consumer use	Paints and coatings	Paint and coating removers	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743, Public comments EPA-HQ-OPPT-2016-0743-0008, EPA-HQ-OPPT-2016-0743-0010, EPA-HQ-OPPT-2016-0743-0011, EPA-HQ-OPPT-2016-0743-0018, EPA-HQ-OPPT-2016-0743-0023, EPA-HQ-OPPT-2016-0743-0025, EPA-HQ-OPPT-2016-0743-0035
		Adhesive removers	Market profile EPA-HQ-OPPT-2016-0743, Public comments EPA-HQ-OPPT-2016-0743-

Life Cycle Stage	Category [a]	Subcategory [b]	References
			0011, EPA-HQ-OPPT-2016-0743-0018
		Lacquers, stains, varnishes, primers and floor finishes	Market profile EPA-HQ-OPPT-2016-0743, Public comments EPA-HQ-OPPT-2016-0743-0018, EPA-HQ-OPPT-2016-0743-0032, EPA-HQ-OPPT-2016-0743-0035
		Powder coatings (surface preparation)	Market profile EPA-HQ-OPPT-2016-0743, Public comments EPA-HQ-OPPT-2016-0743-0016
	Paint additives and coating additives not described by other codes Paint additives and coating additives not described by other codes	Use in Computer and Electronic Product Manufacturing, Construction, Fabricated Metal Product Manufacturing, Machinery Manufacturing, Other Manufacturing, Paint and Coating Manufacturing, Primary Metal Manufacturing, Transportation Equipment Manufacturing, Wholesale and Retail Trade	U.S. EPA (2016b), Public comments EPA-HQ-OPPT-2016-0743-0006, EPA-HQ-OPPT-2016-0743-0007, EPA-HQ-OPPT-2016-0743-0009, EPA-HQ-OPPT-2016-0743-0011, EPA-HQ-OPPT-2016-0743-0013, EPA-HQ-OPPT-2016-0743-0018, EPA-HQ-OPPT-2016-0743-0019, EPA-HQ-OPPT-2016-0743-0023, EPA-HQ-OPPT-2016-0743-0024, EPA-HQ-OPPT-2016-0743-0027, EPA-HQ-OPPT-2016-0743-0031, EPA-HQ-OPPT-2016-0743-0032, EPA-HQ-OPPT-2016-0743-0035, EPA-HQ-OPPT-2016-0743-0036, EPA-HQ-OPPT-2016-0743-0063; EPA-HQ-OPPT-2016-0743-0064
Industrial commercial and consumer use	Solvents (for cleaning or degreasing)	Use in Electrical Equipment, Appliance and Component Manufacturing.	U.S. EPA (2016b), Public comments EPA-HQ-OPPT-2016-0743-0006, EPA-HQ-OPPT-2016-0743-0007, EPA-HQ-OPPT-2016-0743-0009, EPA-HQ-OPPT-2016-0743-0023, EPA-HQ-OPPT-2016-0743-0024, EPA-HQ-OPPT-2016-0743-0027
	Ink, toner and colorant products	Printer ink	U.S. EPA (2016b), Use document, EPA-HQ-OPPT-

Life Cycle Stage	Category [a]	Subcategory [b]	References
	Processing aids, specific to petroleum production Processing aids, specific to petroleum production		2016-0743-0003, Public comments EPA-HQ-OPPT-2016-0743-0006, EPA-HQ-OPPT-2016-0743-0016, EPA-HQ-OPPT-2016-0743-0018
		Inks in writing equipment	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743, Public comment EPA-HQ-OPPT-2016-0743-0018
		Petrochemical Manufacturing	U.S. EPA (2016b), Public comment, EPA-HQ-OPPT-2016-0743-0031
	Adhesives and sealants	Adhesives and sealant chemicals including binding agents	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743, Public comments EPA-HQ-OPPT-2016-0743-0006, EPA-HQ-OPPT-2016-0743-0007EPA-HQ-OPPT-2016-0743-0007, EPA-HQ-OPPT-2016-0743-0011EPA-HQ-OPPT-2016-0743-0011, EPA-HQ-OPPT-2016-0743-0016EPA-HQ-OPPT-2016-0743-0016, EPA-HQ-OPPT-2016-0743-0018EPA-HQ-OPPT-2016-0743-0018, EPA-HQ-OPPT-2016-0743-0023
Industrial commercial and consumer use	Adhesives and sealants	Single component glues and adhesives, including lubricant adhesives	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743, Public comments EPA-HQ-OPPT-2016-0743-0011, EPA-HQ-OPPT-2016-0743-0018, EPA-HQ-OPPT-2016-0743-0035, EPA-HQ-OPPT-2016-0743-0036
		Two-component glues and adhesives, including some resins	U.S. EPA (2016b), Market profile EPA-HQ-OPPT-2016-0743, Public comments EPA-HQ-OPPT-2016-0743-0011, EPA-HQ-OPPT-2016-0743-0016, EPA-HQ-OPPT-2016-0743-0018,

Life Cycle Stage	Category [a]	Subcategory [b]	References
		Soldering materials	Market profile EPA-HQ-OPPT-2016-0743, Public comments EPA-HQ-OPPT-2016-0743-0023
	Other uses	Anti-freeze and de-icing products	U.S. EPA (2016b)
		Automotive care products	U.S. EPA (2016b), Public comment, EPA-HQ-OPPT-2016-0743-0035
		Lubricants and greases	U.S. EPA (2016b)
		Metal products not covered elsewhere	U.S. EPA (2016b), Public comment, EPA-HQ-OPPT-2016-0743-0027, EPA-HQ-OPPT-2016-0743-0028 Public comment, EPA-HQ-OPPT-2016-0743-0027, EPA-HQ-OPPT-2016-0743-0028
		Laboratory chemicals	U.S. EPA (2016b), Public comments EPA-HQ-OPPT-2016-0743-0007, EPA-HQ-OPPT-2016-0743-0009
Industrial commercial and consumer use	Other uses	Lithium ion batteries	Market profile EPA-HQ-OPPT-2016-0743, Public comment EPA-HQ-OPPT-2016-0743-0005
		Cleaning and furniture care products, including wood cleaners, gasket removers	Market profile EPA-HQ-OPPT-2016-0743, Public comment EPA-HQ-OPPT-2016-0743-0025, EPA-HQ-OPPT-2016-0743-0035
		Other uses in Oil and Gas Drilling, Extraction and Support Activities [c]	U.S. EPA (2016b),
		Lubricant and lubricant additives, including hydrophilic coatings	Market profile EPA-HQ-OPPT-2016-0743
		Fertilizer and other agricultural chemical manufacturing - processing aids and solvents	U.S. EPA (2016b), Public comment EPA-HQ-OPPT-2016-0743-0010, EPA-HQ-OPPT-2016-0743-0036

Life Cycle Stage	Category [a]	Subcategory [b]	References
		Pharmaceutical and Medicine Manufacturing - functional fluids (closed systems)	U.S. EPA (2016b), Public comment EPA-HQ-OPPT-2016-0743-0031
		Wood preservatives	Market profile EPA-HQ-OPPT-2016-0743, Public comment EPA-HQ-OPPT-2016-0743-0023
Disposal	Disposal	Industrial pre-treatment	U.S. EPA (2017b)
		Industrial wastewater treatment	
		Publicly owned treatment works (POTW)	U.S. EPA (2017b)
		Underground injection	U.S. EPA (2017b), Public comment EPA-HQ-OPPT-2016-0743-0031
		Landfill (municipal, hazardous or other land disposal)	
		Emissions to air	
		Incinerators (municipal and hazardous waste)	

[a] These categories of conditions of use appear in the life cycle diagram, reflect CDR codes and broadly represent NMP conditions of use in industrial and/or commercial settings.
[b] These subcategories reflect more specific uses of NMP.
[c] Industrial use added to reflect the use of NMP in products in the Oil and Gas Drilling, Extraction This addition to the risk evaluation will help ensure that EPA determines whether NMP presents an unreasonable risk "under the conditions of use," TSCA 6(b)(4)(A).

Although the NMP Scope Document indicated that uses assessed in the 2015 risk assessment would not be re-evaluated (EPA-HQ-OPPT-2016-0743), EPA has decided to include these conditions of use in the risk evaluation as described in this problem formulation. EPA is including these conditions of use so that they are part of EPA's determination of whether NMP may present an unreasonable risk "under the conditions of use," TSCA 6(b)(4)(A). EPA has concluded that the Agency's assessment of the potential risks from this widely used chemical will be more robust if the risks from these conditions of use are evaluated by applying the standards and guidance provided under amended TSCA. This includes ensuring the evaluation is consistent with the scientific standards in Section 26 of TSCA, the Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (40 CFR Part 702) and EPA's supplemental document, *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration. It is important to note that conducting these evaluations does not preclude EPA from finalizing the proposed NMP regulation (82 FR 7464).

2.2.2.3 Overview of Conditions of Use and Life Cycle Diagram

The life cycle diagram provided in Figure 2-1 depicts the conditions of use that are considered within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, distribution, use (industrial, commercial, and consumer) and disposal. Additions or changes to conditions of use based on additional information gathered or analyzed during problem formulation are described further in Sections 2.2.2.1 and 2.2.2.2. The information is grouped according to Chemical Data Reporting (CDR) processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses), in combination with other data sources (e.g., published literature and consultation with stakeholders), to provide an overview of conditions of use. EPA notes that some subcategories of use may be grouped under multiple CDR categories.

Use categories include the following: "industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed. "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services. "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use (U.S. EPA, 2016b).

To understand conditions of use relative to one another and the associated exposure potential under those conditions of use, the life cycle diagram includes the production volume associated with each stage of the life cycle, as reported during the 2016 CDR reporting period (U.S. EPA, 2016b), when the volume was not claimed confidential business information (CBI).

The 2016 CDR reporting data for NMP are provided in Table 2-4 from EPA's CDR database. This information has not changed from that provided in the scope document.

Table 2-4. Production Volume of NMP in CDR Reporting Period (2012 to 2015) [a]

Reporting Year	2012	2013	2014	2015
Total Aggregate Production Volume (lbs)	164,311,844	168,187,596	171,095,221	160,818,058

[a] The CDR data for the 2016 reporting period is available via ChemView (https://java.epa.gov/chemview) (U.S. EPA, 2016b). Because of an ongoing CBI substantiation process required by amended TSCA, the CDR data available in the scope document is more specific than currently in ChemView.

Descriptions of the industrial, commercial and consumer use categories identified from the 2016 CDR (U.S. EPA, 2016b) and included in the life cycle diagram are summarized below. The descriptions provide a brief overview of the use category; Appendix B contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams, equipment illustrations) for each manufacture, processing, use and disposal category. The descriptions provided below are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions from the 2016 CDR and can be found in EPA's *Instructions for Reporting 2016 TSCA Chemical Data Reporting* (U.S. EPA, 2016a).

The "**Paints and Coatings**" category encompasses chemical substances contained in products that are used in a variety of coatings including paints, glazes, grouts, hydrophilic coatings, stains and wood preservatives. Removers of paints and coatings also fall into this category. Products in this category

have applications in industrial, commercial and consumer settings and are available in both liquid and aerosol formulations.

The "**Solvents for Cleaning and Degreasing**" category encompasses various chemical substances used to dissolve oil, grease and similar materials from a variety of substrates including metal surfaces, glassware and textiles. This category includes industrial, commercial and consumer uses of NMP for cleaning electrical equipment, gaskets, leather and other textiles, as well as a variety of other substrates. This category also includes chemical substances used as solvents during the production of electronic products and lithium ion batteries. Most NMP formulations in this category are liquid, but aerosol cleaning formulations are also available.

The "**Ink, Toner and Colorant Products**" category encompasses chemical substances that are contained in products used for printer inks and toners. Specifically, NMP can be found as a component of ink thinners, weather resistant markers for polyurethane tags and inks used in 3D printers. NMP is also found in inks used within industrial, commercial and consumer settings, and is typically formulated as a liquid.

The "**Processing Aids, Specific to Petroleum Production**" category encompasses chemical substances which are used to aid in the production of petrochemical, plastic and rubber products. This category is primarily industrial, and formulations are liquid.

The "**Adhesives and Sealants**" category encompasses chemical substances contained in adhesive and sealant products used to fasten other materials together. NMP is used as an adhesive or sealant for a wide variety of products including: pressure-sensitive adhesives, polyurethane curatives, floor sealants and sealants for automotive parts. These products have industrial, commercial and consumer applications and can be found in liquid, solid and aerosol formulations.

The **"Other uses"** category covers a wide variety of products containing NMP, including automotive care products, deicers as well as NMP use in laboratory settings. EPA notes that some of the uses identified for NMP may be considered critical to national security. These uses and their importance to national security will be considered during the risk evaluation, and as part of any resulting regulatory actions the Agency may deem necessary to protect human health and the environment.

Figure 2-1 depicts the life cycle diagram of NMP, from manufacturing to the point of disposal. Activities related to distribution (e.g., loading, unloading) will be considered throughout the NMP life cycle, rather than using a single distribution scenario.

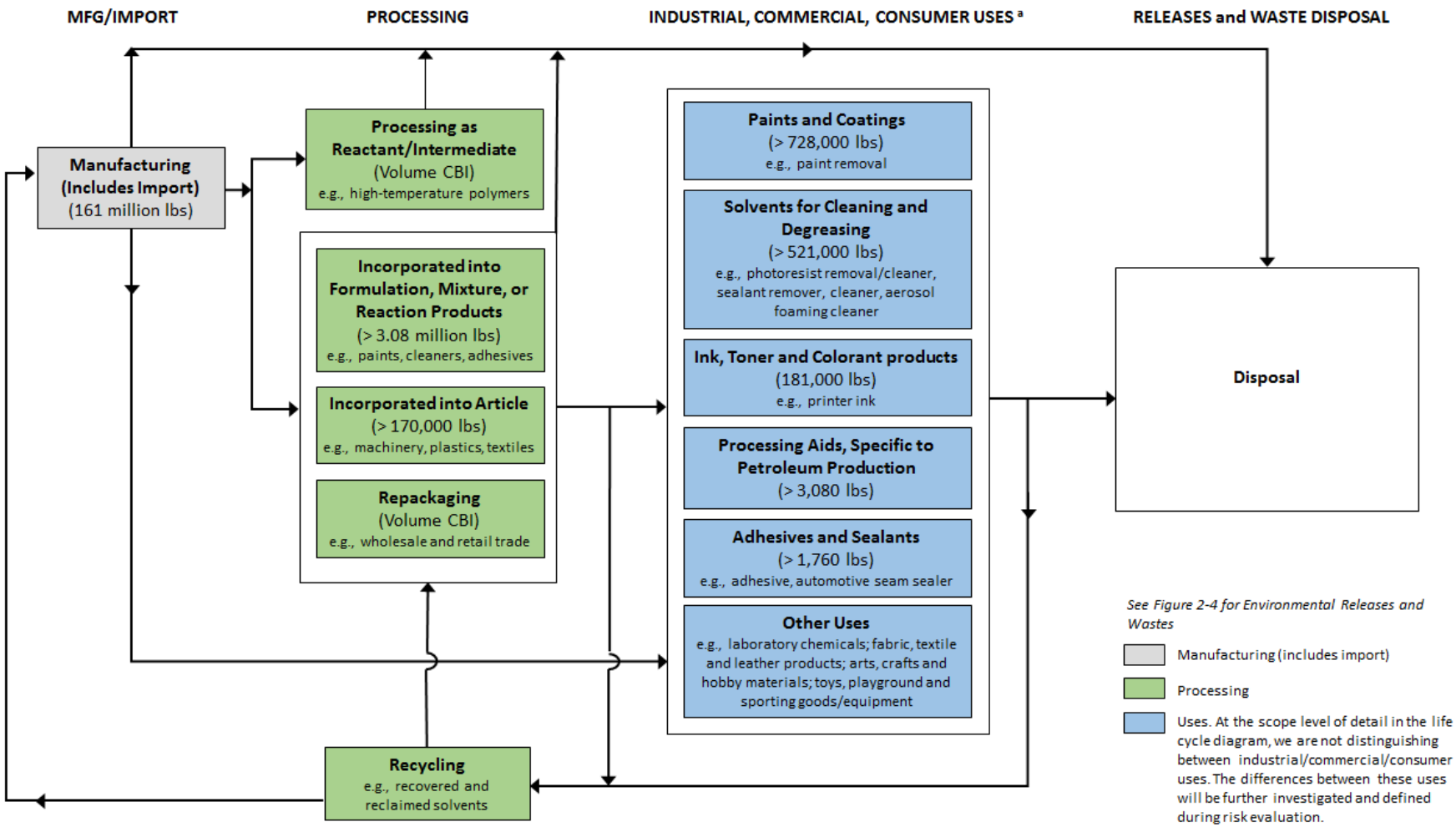


Figure 2-1. NMP Life Cycle Diagram

The life cycle diagram depicts the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, distribution, use and disposal. The production volumes shown are for reporting year 2015 from the 2016 CDR reporting period (U.S. EPA, 2016b). Activities related to distribution (e.g., loading, unloading) will be considered throughout the NMP life cycle, rather than using a single distribution scenario.

[a] See Table 2-3 for additional uses not mentioned specifically in this diagram.

2.3 Exposures

For TSCA exposure assessments, EPA expects to evaluate exposures and releases to the environment resulting from the conditions of use applicable to NMP. Post-release pathways and routes will be described to characterize the relationship or connection between the conditions of use for NMP and the exposure to receptors, including potentially exposed or susceptible subpopulations and ecological receptors. EPA will take into account, where relevant, the duration, intensity (concentration), and frequency of exposures in characterizing exposures to NMP.

2.3.1 Fate and Transport

Environmental fate includes both transport and transformation processes. Environmental transport is the movement of the chemical within and between environmental media. Transformation occurs through the degradation or reaction of the chemical with other species in the environment. Hence, knowledge of the environmental fate of the chemical informs the determination of the specific exposure pathways and potential human and ecological receptors EPA expects to consider during risk evaluation. Table 2-5 provides environmental fate data that EPA identified and considered in developing the scope for NMP. This information has not changed from that provided in the scope document.

During problem formulation, fate data including information pertaining to volatilization during wastewater treatment, volatilization from lakes and rivers, biodegradation rates and the organic carbon:water partition coefficient (log K_{OC}) were used when considering changes to the conceptual models. Model results and basic principles were used to support the fate data while relevant literature is evaluated via the systematic review process.

EPI Suite™ modules were used to predict volatilization of NMP from wastewater treatment plants, lakes, and rivers (U.S. EPA, 2012b). The EPI Suite™ module that estimates chemical removal in sewage treatment plants ("STP" module) was run using default settings to evaluate the potential for NMP to biodegrade, volatilize to air or adsorb to sludge during wastewater treatment. The STP module, using BIOWIN predictions for biodegradation rates, estimates that most (> 90%) of the NMP releases to wastewater will be removed by biodegradation. BIOWIN model predictions further indicate negligible (< 1%) removal of NMP via adsorption to sludge or volatilization to air.

The EPI Suite™ module that estimates volatilization from lakes and rivers ("Volatilization" module) was run using default settings to evaluate the potential for NMP to volatilize from surface water. The input parameters required for estimating the volatilization (evaporation) rate of an organic chemical from a water body are water depth, wind speed and current velocity of a river or lake. The model results indicate that volatilization from surface water is unlikely to be a significant removal pathway for NMP (U.S. EPA, 2012b). Aerobic biodegradation is expected to be the primary removal pathway for NMP in many surface water environments based on measured data (see Table 2-5).

Experimental data and EPISuite™ model predictions indicate that NMP will degrade in aerobic environments (U.S. EPA, 2012b); however, the BIOWIN module within EPISuite™ that estimates anaerobic biodegradation potential (BIOWIN 7) predicts that NMP will not rapidly biodegrade under anaerobic conditions. These model predictions are consistent with previous NMP assessments (OECD, 2007; WHO, 2001; U.S. EPA, 1998b).

Table 2-5. Environmental Fate Characteristics of NMP

Property or Endpoint	Value [a]	Reference
Direct photo-degradation	Not available	
Indirect photo-degradation	5.8 hours (estimated for atmospheric degradation)	U.S. EPA (2015)
Hydrolysis half-life	Does not undergo hydrolysis	U.S. EPA (2015)
Biodegradation	99% (duration not indicated) (aerobic in water, coupled-units) 50% in < 12 days (aerobic in soil) 95% removal in 2 weeks (aerobic in static die-away system test, sewage sludge inoculum, OECD 301A) 95% in 7 days (SCAS, OECD 303A)	U.S. EPA (1998b)
	73% in 28 days (aerobic in water, Modified Ministry of International Trade and Industry (MITI), OECD 301C) 91-97% in 28 days (aerobic, Sturm, OECD 301B) 98% in 4 days (aerobic in water and sludge, Zahn-Wellens, OECD 302B) 88% in 30 days (closed-bottle test, OECD 301D) 99% in 19 days (modified screening, OECD 301E)	U.S. EPA (2015)
Bioconcentration factor (BCF)	3.16 (estimated)	U.S. EPA (2015)
Bioaccumulation factor (BAF)	0.9 (estimated)	U.S. EPA (2012b)
Soil organic carbon/water partition coefficient (log K_{oc})	0.9 (estimated)	U.S. EPA (2012b)

[a] Measured unless otherwise noted.

NMP does not persist in the environment. Upon release into the atmosphere, it is expected to biodegrade via reaction with photo-chemically produced hydroxyl radicals in ambient air. The half-life for this reaction is approximately 5.8 hours, assuming a hydroxyl radical concentration of 1.5×10^6 hydroxyl radicals/cm^3 air and a 12-hour day (U.S. EPA, 2015). NMP is hygroscopic and can dissolve in water droplets. Atmospheric releases may be removed via condensation, wet deposition or further reaction with hydroxyl radicals.

Although neat (pure) NMP is slightly volatile, volatilization from water and moist soils is not likely based on its Henry's Law constant (3.2×10^{-9} atm m^3/mole). NMP is not expected to adsorb to suspended solids or sediment upon release to water due to its estimated soil organic carbon/water partition coefficient (log K_{oc} = 0.9). NMP exhibits high mobility in soil; hence, environmental releases are expected to migrate from soil to ground water (U.S. EPA, 2012b).

NMP exhibits low potential for bioaccumulation in the environment. Measured bioconcentration studies for NMP were not presented in EPA's previous evaluation of risks associated with NMP use in paint and coating removal (U.S. EPA, 2015); however, based on the estimated BAF and BCF values (0.9 and 3.16,

respectively), NMP is not expected to bioaccumulate or bioconcentrate in aquatic organisms (U.S. EPA, 2012b, 1999); OECD, 2007, 3809443}.

2.3.2 Releases to the Environment

Releases to the environment from conditions of use (e.g., industrial and commercial processes, commercial or consumer uses resulting in down-the-drain releases) are one component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data and/or assumptions and models.

A source of information EPA expects to consider for evaluating exposures are data reported under the Toxics Release Inventory (TRI) program. Under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313, NMP is a TRI-reportable substance effective January 1, 1995. During problem formulation EPA further analyzed the TRI data and examined the definitions of elements in the TRI data to determine the level of confidence that a release would result from specific types of disposal to land (e.g., RCRA Subtitle C hazardous landfill and Class I underground Injection wells) and incineration. EPA also examined how NMP is treated at industrial facilities.

Table 2-6 provides production-related waste management data (also referred to as waste managed) for NMP reported by industrial facilities to the TRI program for 2015. Table 2-7 provides more detailed information on the actual quantities of NMP released to air and water or disposed of on land.

Table 2-6. Summary of NMP TRI Production-Related Waste Managed in 2015 (lbs)

Number of Facilities	Recycling	Energy Recovery	Treatment	Releases [a, b, c]	Total Production Related Waste
386	47,453,751	7,603,919	14,944,336	8,807,902	78,819,909

Data source: 2015 TRI Data (updated March 2017) (U.S. EPA, 2017b).
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] Does not include releases due to a one-time event not associated with production such as remedial actions or earthquakes.
[c] Counts all releases including release quantities transferred and those disposed of by a receiving facility reporting to TRI.

In 2015, 386 facilities reported a total of 78.8 million pounds of NMP waste managed. Of this total, over 47.5 million pounds of NMP were recycled; 34 TRI facilities reported recycling NMP on-site and 85 facilities reported distribution of NMP off-site for recycling, representing approximately 60% of the total waste managed. In addition, approximately 7.6 million pounds of NMP was used for energy recovery; 14.9 million pounds were treated and 8.8 million pounds were released to the environment.

Table 2-7. Summary of NMP TRI Releases to the Environment in 2015 (lbs)

		Air Releases			Land Disposal				
	Number of Facilities	Stack Air Releases	Fugitive Air Releases	Water Releases	Class I Under-ground Injection	RCRA [a] Subtitle C Landfills	All other Land Disposal [b]	Other Releases [b]	Total Releases [c]
Subtotal		884,851	542,101		3,625,939	93,217	2,719,441		
Total	386	1,426,952		14,092	6,438,597			28,099	8,108,070

Data source: 2015 TRI Data (updated March 2017) (U.S. EPA, 2017b).
[a] RCRA (Resource Conservation and Recovery Act)

	Number of Facilities	Air Releases		Water Releases	Land Disposal			Other Releases [b]	Total Releases [c]
		Stack Air Releases	Fugitive Air Releases		Class I Under-ground Injection	RCRA [a] Subtitle C Landfills	All other Land Disposal [b]		

[b] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[c] These release quantities do include releases due to one-time events not associated with production such as remedial actions or earthquakes.

Roughly 79% (~ 6.4 million pounds) of the environmental releases reported for NMP in 2015 were to land, 18% (~ 1.4 million pounds) were to air (stack and fugitive emissions), and 0.2% (~14,000 pounds) were discharged to water (Table 2-7). The stack releases reported to TRI represent the total amount of NMP air releases from stacks, confined vents, ducts, pipes or other confined air streams. Many facilities reported stack air releases from NMP destruction via incineration, including hazardous waste facilities and facilities that perform other industrial activities (i.e., federal, state or municipal). These estimates likely represent decomposition products, as NMP destruction via incineration is highly efficient.

Most of the on-site land disposal reported for NMP in 2015 was to Class I underground injection wells (~ 3.6 million pounds). Only 13 pounds went to on-site landfills other than RCRA Subtitle C Landfills and other land disposal. No NMP was reported as disposed on-site in Class II-V underground injection wells, on-site land treatment, or on-site surface impoundments. Most off-site releases (~ 2.7 million pounds) went to landfills other than RCRA Subtitle C Landfills. Other release amounts were reported as transfers to RCRA Subtitle C Landfills (~ 93,217 pounds), other land disposal types (~ 25,648 pounds) and off-site land treatment (~ 330 pounds).

While the production-related waste managed shown in Table 2-6 excludes any quantities reported as catastrophic or one-time releases (TRI Section 8 data), release quantities shown in Table 2-7 include both production-related and non-routine quantities (TRI Section 5 and 6 data). As a result, release quantities may differ slightly and may further reflect differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2016c).

EPA is aware of additional sources of information for NMP release data, such as assessments from other countries. and the Discharge Monitoring Report (DMR) Pollutant Loading Tool, which provides additional information on releases to surface water. For example, the 2011 European Chemicals Agency (ECHA) Dossier on the identification of NMP as a substance of very high concern includes a compilation of the conditions of use for NMP, along with some discussion of potential sources of environmental release information. The DMR loading tool calculates pollutant loadings from permit and DMR data from EPA's Integrated Compliance Information System for the National Pollutant Discharge Elimination System. The limited DMR data available for NMP will be further analyzed during risk evaluation.

2.3.3 Presence in the Environment and Biota

Monitoring studies or a collection of relevant and reliable monitoring studies provide(s) information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure. Limited environmental monitoring data were identified in EPA's data search for NMP.

EPA has developed an electronic STOrage and RETrieval system for water quality monitoring data known as STORET, which maps monitoring sites and allows for download of sampling data of surface water monitoring sites (U.S. EPA, 2012c). In addition, the Water Quality Portal, a cooperative service sponsored by the U.S. Geological Survey (USGS), EPA and the National Water Quality Monitoring Council (NWQMC, 2017) provide both STORET data and surface water and ground water monitoring data from USGS. An initial search within the STORET system listed NMP as a sampled parameter, but did not include any site-specific information for NMP (NWQMC, 2017).

NMP has been detected in industrial landfill leachate (Danish EPA, 2015). Although it is not currently subject to any proposed or promulgated water regulations, NMP has been detected in wastewater (WHO, 2001) and is included on EPA's Drinking Water Contaminant Candidate Lists (CCL) 3 and 4 because it is a suspected contaminant in public water systems that may require regulation under the Safe Drinking Water Act (SDWA) (74 FR 51850, October 8, 2009 and 81 FR 81099 November 16, 2016).

The Air Quality System contains air pollution monitoring data collected by EPA, as well as state, local and tribal agencies. A preliminary search of this database revealed that NMP is not a pollutant included in national, state or tribal ambient air monitoring programs.

According to the Environment Canada and Health Canada Draft Screening Assessment, NMP has been monitored in indoor air samples in Canada. NMP air concentrations associated with carpet and rubber-based flooring were reported in a Canadian study on indoor air releases from building materials and furnishings. NMP also was detected in air and dust samples collected from homes during a field study in Quebec (EC/HC, 2017).

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of NMP can result in releases to the environment. In this section, EPA presents exposures to aquatic and terrestrial organisms.

Aquatic Exposures

EPA did not identify water monitoring data for NMP during its review of the national surface water monitoring database. The 2015 TRI data on direct and indirect environmental releases were used to estimate NMP concentrations in surface water. Direct releases represent environmental releases of NMP that are discharged directly from a facility into a receiving water body (after treatment), whereas indirect releases represent discharges to surface water that occur following treatment at a municipal wastewater facility.

To capture "high-end" surface water concentrations, EPA compiled the release data for six facilities that reported the largest NMP direct water releases. This represented > 99% of the total volume of NMP reported as a direct discharge to surface water during the 2015 TRI reporting period. Since there were many more facilities reporting indirect releases of NMP to surface water, seven of the facilities reporting the largest indirect water releases (representing ~ 11% of the total number of facilities reporting indirect discharges) were compiled. The volume of NMP released from these facilities encompassed more than 68% of the total volume of NMP reported as an indirect discharge to surface water (see Appendix C).

For problem formulation, EPA used release data reported in the 2015 TRI to predict surface water concentrations near the associated reporting facilities. To examine whether (near-facility) surface water concentrations may present a risk concern for aquatic organisms, EPA employed a first-tier screening approach, utilizing readily-available data, modeling tools and conservative assumptions.

EPA's Probabilistic Dilution Model (PDM) was used to estimate site-specific surface water concentrations based on the 2015 TRI data for "on-site" NMP releases to surface waters (U.S. EPA, 2007). The reported TRI releases were based on available information including monitoring data, emission factors, mass balance and/or other engineering calculations. The PDM also incorporates wastewater treatment removal efficiency. For this analysis, wastewater treatment removal efficiency was conservatively assumed to be 0%, as the reported NMP water releases were assumed to account for wastewater treatment *a priori*. Further, as the total days of release were not reported in these sources, EPA assumed a range of possible release days (i.e., 12 and 250 days/year) for facilities directly discharging NMP to surface water and 250 days/year for indirect discharges from wastewater treatment plants or Publicly Owned Treatment Works (POTWs) receiving indirect discharges of NMP).

The "high-end" surface water concentrations (i.e., those obtained assuming a low stream flow for the receiving water body) from all PDM runs ranged from 224 µg/L to 0.00005 µg/L, for the acute (i.e., assumed fewer than 20 days of environmental releases per year) and chronic exposure scenario (i.e., more than 20 days of environmental releases per year assumed), respectively. The maximum acute scenario concentration was 224 µg/L and the maximum chronic scenario concentration was 11 µg/L. For a full table of results, see Table_Apx C-1 in Appendix C.

Terrestrial Exposures

Terrestrial populations living near industrial and commercial facilities that use NMP may be exposed via multiple routes. EPA did not identify monitoring data for NMP releases to the environment; however, the 2015 TRI data indicate that most of the reported releases were landfilled or injected underground.

2.3.5 Human Exposures

In this section EPA presents information on occupational, consumer and general population exposures. Subpopulations within these exposed groups, including potentially exposed or susceptible subpopulations, are also presented.

2.3.5.1 Occupational Exposures

Exposure pathways and exposure routes are listed below for worker activities under the various conditions of use (industrial or commercial) described in Section 2.2. In addition, exposures to occupational non-users (i.e., individuals who do not directly handle NMP, but perform work in an area where it is present) are also listed. Engineering controls and/or personal protective equipment may impact occupational exposure levels.

In the previous risk assessment (U.S. EPA, 2015), EPA assessed dermal and inhalation exposures associated with occupational use of NMP in paint and coating removal. These uses and exposure pathways will be further considered during risk evaluation.

Workers and occupational non-users may be exposed to NMP when performing activities associated with the conditions of use described in Section 2.2 including, but not limited to:

- Unloading and transferring NMP to and from storage containers to process vessels;
- Using NMP in process equipment (e.g., applying photoresists during silicon wafer production);
- Applying formulations and products containing NMP onto substrates (e.g., applying adhesives, sealants and NMP-containing products that facilitate their removal);
- Cleaning and maintaining equipment;
- Sampling chemical formulations or products containing NMP for quality control
- Repackaging chemical formulations or products containing NMP

- Handling, transporting and disposing wastes containing NMP;
- Performing other work activities in or near areas where NMP is used.

Key Data
Key data that inform occupational exposure assessment include the Occupational Safety and Health Administration (OSHA) Chemical Exposure Health Data (CEHD) and National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluation (HHE) program data. OSHA data are workplace monitoring data from OSHA inspections. OSHA data can be obtained through CEHD https://www.osha.gov/opengov/healthsamples.html. Table_Apx B-1and Table_Apx B-2 in Appendix B provide a summary of the monitoring data available for NMP (air samples obtained from OSHA inspections conducted between 2011 and 2016). NIOSH HHEs are conducted at the request of employees, union officials, or employers and help inform potential hazards at the workplace. HHEs can be downloaded at https://www.cdc.gov/niosh/hhe/. Table_Apx B-3 provides a summary of the NMP air monitoring data obtained from NIOSH HHEs. EPA will review these data and evaluate their utility during risk evaluation.

There is a potential for dermal and inhalation exposures to NMP in the workplace (including contact with liquid, aerosol mist and vapor forms of NMP)**.** OSHA has not established regulatory exposure limits for NMP. The only recommended exposure limit identified for NMP is a non-regulatory limit established by the American Industrial Hygiene Association (AIHA): a workplace environmental exposure level (WEEL) of 10 ppm as an 8-hour (hr) time weighted average (TWA), with the addition of a cautionary note addressing concerns for skin contact. Additional information can be obtained at https://www.tera.org/OARS/WEEL.html.

Dermal
Based on the occupational exposure scenarios identified in Table 2-3, EPA expects a potential for worker exposure via skin contact with NMP (liquid, vapor, mist or dust). Because NMP is readily absorbed through the skin, dermal exposures can significantly impact body burden. Dermal exposure is therefore expected to be an important pathway for workers and occupational non-users (i.e., vapor-through-skin exposure).

Inhalation
Although NMP has a relatively low vapor pressure, some conditions of use identified in Table 2-3 may present a concern for inhalation exposure to workers and occupational non-users, particularly those that involve vaporization or spray application. Exposures can also occur from NMP (i.e., vapor, mist, dust) that deposits in the upper respiratory tract. Because NMP is expected to be rapidly absorbed at the point of contact, materials deposited in the upper airway will be considered as an inhalation exposure.

2.3.5.2 Consumer Exposures

NMP can be found in consumer products and/or commercial products that are readily available for purchase at common retailers (EPA-HQ-OPPT-2016-0743-0003, Sections 3 and 4 and Table 2-3) and can therefore result in exposures to consumers and bystanders (non-users who are incidentally exposed to NMP as a result of consumer product use).

In the previous risk assessment (U.S. EPA, 2015), EPA investigated dermal and inhalation exposures from consumer use of NMP-containing products during paint and coating removal. EPA modeled exposures to consumers and bystanders using a variety of indoor exposure scenarios that varied specific input parameters including (but not limited to) the product formulation (NMP weight fraction), method

of application (i.e., brush vs. spray), and duration of use (U.S. EPA, 2015). The conditions of use assessed in the previous NMP assessment will be further considered during risk evaluation.

Dermal
EPA expects dermal exposure to be a significant route of exposure for consumers and bystanders. Dermal exposure to consumers may occur from direct contact with NMP-containing liquids or from deposition onto skin (e.g., vapor, mist or dust). Direct skin contact with NMP-containing liquids could be concurrent with vapor-through-skin exposures for some conditions of use, particularly those that involve heating or spray application. The frequency/duration and extent of exposure (i.e., surface area of exposed skin) are expected to significantly impact body burden. Bystanders are not expected to have direct contact with NMP-containing liquids, but may be exposed via skin deposition.

Inhalation
Although NMP has a low vapor pressure, there is potential for inhalation exposure to consumers and bystanders during heating or spray application of products that contain NMP. Exposures to consumers and bystanders may also occur through ingestion of airborne materials that deposit in the upper respiratory tract. EPA assumes these exposures are absorbed via inhalation.

Oral
There is potential for oral exposure to consumers from contact with NMP-containing products via hand-to-mouth activity. Mouthing behaviors may also be an important consideration, especially for children. The frequency and duration of these activities and the NMP content in related products can significantly impact exposure potential. During risk evaluation. EPA expects to further analyze oral exposures to consumers that may result from incidental ingestion of NMP during use of formulations, products or other articles that contain NMP (e.g., children's toys, arts and crafts kits, games, bedding, textiles, and kitchenware).

EPA's previous assessment of NMP use in paint and coating removal did not include an evaluation of oral exposure to consumers, which may have resulted in an underestimation of the total exposure potential for this population. During problem formulation, EPA reviewed publicly available consumer product data (e.g., the Centers for Disease Control Household Database and the Chemical and Product Categories database). Based on the use categories listed in Table 2-3, a table of preliminary exposure scenarios was developed to map the associated conditions of use and exposure pathways identified for NMP (see Appendix Table_Apx E-1. Supporting Table for Consumer Activities and Uses Conceptual Model).

2.3.5.3 General Population Exposures

Wastewater/liquid wastes, solid wastes or air emissions of NMP could result in potential pathways for oral, dermal or inhalation exposure to the general population

Oral
Oral exposure to NMP is expected to be a relevant route of exposure for the general population. Individuals may be exposed to NMP levels that occur in drinking water and/or well water. EPA was unable to locate monitoring data for NMP levels in the ambient environment; however, wet deposition from air could be a significant (air-to-ground) removal pathway. NMP exhibits high mobility in soil; environmental releases are ultimately expected to migrate to water.

Dermal
General population exposure to NMP may occur through dermal contact with NMP concentrations in drinking water and/or well water during bathing, or from public recreation in impacted waterways.

Inhalation
Inhalation is expected to be a relevant route of exposure for the general population due to the propensity for NMP air releases from ongoing commercial and industrial activities. Limited information was identified for air emissions resulting from NMP use in industrial operations.

2.3.5.4 Potentially Exposed or Susceptible Subpopulations

TSCA requires the determination of whether a chemical substance presents an unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation" by EPA. TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011).

As part of problem formulation, EPA identified potentially exposed or susceptible subpopulations for further analysis during the development and refinement of the conceptual models, exposure scenarios and analysis plan. In this section, EPA addresses the potentially exposed or susceptible subpopulations identified as relevant based on greater exposure. EPA will address the subpopulations identified as relevant based on greater susceptibility in the hazard section.

EPA identifies the following as potentially exposed or susceptible subpopulations that EPA expects to consider in the risk evaluation due to their *greater exposure*:

- Workers and occupational non-users;
- Consumers and bystanders associated with consumer use. NMP has been identified in products available to consumers; however, only some individuals within the general population may use these products. Therefore, those who do use these products represent a potentially exposed or susceptible subpopulation due to greater exposure.
- Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, use or disposal sites).

In developing exposure scenarios, EPA will analyze available data to ascertain whether some human receptor groups may be exposed via pathways that may be distinct to a particular subpopulation or life stage and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006b).

In summary, in the risk evaluation for NMP, EPA expects to analyze the following potentially exposed groups of human receptors: workers, occupational non-users, consumers, bystanders associated with consumer use and other groups of individuals within the general population who may experience greater

exposure. EPA may also identify additional potentially exposed or susceptible subpopulations that will be considered based on greater exposure.

2.4 Hazards (Effects)

For scoping, EPA conducted comprehensive searches for data on hazards of NMP, as described in the *Strategy for Conducting Literature Searches for NMP: Supplemental File for the TSCA Scope Document* EPA-HQ-OPPT-2016-0743). Based on initial screening, EPA expects to analyze the hazards of NMP identified in this problem formulation document. However, when conducting the risk evaluation, the relevance of each hazard within the context of a specific exposure scenario will be judged for appropriateness. For example, hazards that occur only as a result of chronic exposures may not be applicable to acute exposure scenarios. Thus it is unlikely that all identified hazards will be considered for every exposure scenario.

2.4.1 Environmental Hazards

EPA identified the following sources of environmental hazard data for NMP: U.S. EPA (2006a), OECD (2007), (U.S. EPA, 2015), (Danish EPA, 2015), EC/HC (2017) and Ecological Hazard Literature Search Results in the *NMP (CASRN 872-50-4) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0743). Only the *on-topic* references listed in the Ecological Hazard Literature Search Results were considered as potentially relevant data/information sources for the risk evaluation. Inclusion criteria were used to screen the results of the ECOTOX literature search (as explained in the *Strategy for Conducting Literature Searches for NMP: Supplemental Document to the TSCA Scope* document, *CASRN 872-50-4*). Data from the screened literature are summarized below (**Table 2-8**) as ranges (min-max). EPA expects to review these data/information sources during risk evaluation using the data quality review evaluation metrics and the rating criteria described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

Acute Toxicity to Aquatic Organisms

The acute 96-hour LC_{50} values reported for fish range from >500 mg/L Rainbow trout (*Oncorhynchus* mykiss) to 4,030 mg/L for Orfe (*Leuciscus idus*). Four acute toxicity studies with aquatic invertebrates have been identified; two used the water flea and two studies used grass shrimp as the test species. The 48-hr EC_{50} for water fleas ranged from 1.23 to 4,897 mg/L, whereas the reported 48-hr EC_{50} for grass shrimp ranged from > 299 to 1,107 mg/L. For green algae, the 72-hr EC_{50} values ranged from > 500 to 600.5 mg/L.

Chronic Toxicity to Aquatic Invertebrates

Chronic aquatic toxicity data are available for NMP. From a 21-day study with *Daphnia magna*, the chronic toxicity value was calculated as 17.68 mg/L based on reproduction (using the NOEC value of 12.5 mg/L and the LOEC value of 25 mg/L).

Toxicity to Sediment and Terrestrial Organisms

EPA did not identify data on NMP hazards to sediment invertebrates, or terrestrial organisms including soil invertebrates; however, based on the physical-chemical and fate properties of NMP, accumulation in these environmental compartments is unlikely (see Section 2.3.1). NMP exposure to soil- or sediment-dwelling organisms is not expected to be significant; therefore, hazards to these organisms will not be analyzed further during risk evaluation (see Section 2.3.4).

Table 2-8. Ecological Hazard Characterization of NMP

Duration	Test organism	Endpoint	Hazard value*	Units	Effect Endpoint	Reference
Aquatic Organisms						
Acute	Fish	LC_{50}	>500-4030	mg/L	Mortality	(BASF, 1983) as cited in OECD (2009b); (BASF, 1986) as cited in OECD (2009b)
	Aquatic invertebrates	EC_{50}	1.23 - 4897	mg/L	Immobilization	Lan et al. (2004); GAF (1979) as cited in OECD (2009b)
	Algae	EC_{50}	> 500-600.5	mg/L	Growth	(ECHA, 2014b)
	Acute COC	0.246 mg/L				
Chronic	Fish	ChV	-	mg/L		
	Aquatic invertebrates	NOEC LOEC ChV	12.5 25 17.68	mg/L	Reproduction	BASF AG (2001) as cited in OECD (2009b)
	Algae	ChV	125 (NOEC)	mg/L		(ECHA, 2014b)
	Chronic COC	1.768 mg/L				
Terrestrial Organisms						
Acute	Avian	LD50	2500-5000	mg/kg-bw	Mortality	Hazelton Lab (1980) as cited in OECD (2009b)

* Values in the tables are presented as reported by the study authors; - = endpoint not addressed

Concentrations of Concern

The screening-level acute and chronic concentrations of concern (COCs) for NMP were derived based on the lowest or most toxic ecological toxicity values (e.g., L/EC50). The information below describes how the acute and chronic COC's were calculated for environmental toxicity of NMP using assessment factors.

The application of assessment factors is based on established EPA/OPPT methods (U.S. EPA, 2013, 2012d) and were used in this hazard assessment to calculate lower bound effect levels (referred to as the concentration of concern; COC) that would likely encompass more sensitive species not specifically represented by the available experimental data. Also, assessment factors are included in the COC calculation to account for differences in inter- and intraspecies variability, as well as laboratory-to-field variability. It should be noted that these assessment factors are dependent upon the availability of datasets that can be used to characterize relative sensitivities across multiple species within a given taxa or species group, but are often standardized in risk assessments conducted under TSCA, since the data available for most industrial chemicals is limited.

The concentrations of concern for each endpoint were derived based on the ecological hazard data for NMP. The information below describes how the acute and chronic COCs were calculated for aquatic toxicity.

The acute COC is derived by dividing the aquatic invertebrates 48-hr EC50 of 1.23 mg/L (the lowest acute value in the dataset) by an assessment factor of 5:

- Lowest acute value for 48-hr aquatic invertebrates EC50 (1.23 mg/L)/5 = 0.246 mg/L (246 µg/L)

The acute COC of 246 µg/L, derived from the experimental aquatic invertebrate endpoint, is used as a conservative hazard level for NMP in this problem formulation.

The chronic COC was determined based on the lowest chronic toxicity value divided by an assessment factor of 10:

- Lowest chronic value for (21-day) Daphnia = 17.68 mg/L/10 = 1.768 mg/L (1,768 µg/L)

The chronic COC of 1,768 µg/L, derived from the experimental aquatic invertebrate endpoint, is used as the lower bound hazard level for NMP in this problem formulation.

2.4.2 Human Health Hazards

EPA recently published a risk assessment on NMP use in paint and coating removal, hence many of the hazards of NMP exposure have been compiled and reviewed (U.S. EPA, 2015). EPA relied heavily on this comprehensive review in preparing the current problem formulation document. Numerous human health hazards have been identified for NMP including adverse effects on hepatic, renal, immune, reproductive/developmental and central nervous systems (RIVM, 2013; OECD, 2007; WHO, 2001). EPA expects to use the previous review as a starting point for identifying both key and supporting studies that will be used to inform hazard characterization, including dose-response analysis. The relevant studies will be evaluated using the data quality criteria in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018). EPA also expects to consider studies that have been published since this review, as identified in the literature search conducted by the Agency (*NMP (CASRN 872-50-4) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0743). Based on reasonably available information, the following sections briefly describe the potential hazards that may be associated with NMP exposure.

2.4.2.1 Non-Cancer Hazards

Irritation and Sensitization

NMP is a skin, eye and possible respiratory irritant. Although the available sensitization data have significant limitations, there are multiple studies of NMP in humans with no reports of sensitization following NMP exposure (RIVM, 2013).

Acute Toxicity

The acute toxicity of NMP is expected to be low based on results from laboratory animal studies including oral, dermal, inhalation, intraperitoneal and intravenous routes of exposure in rats and mice (RIVM, 2013; OECD, 2007; WHO, 2001).

Systemic Effects

Systemic effects observed following oral repeated-dose toxicity testing include body weight reductions, alterations in hematology and clinical chemistry parameters, liver and kidney toxicity, neurotoxicity and thymic atrophy. More severe effects have been noted following whole-body inhalation exposure (which includes dermal and oral uptake), including bone marrow hypoplasia, testicular effects, necrosis of lymphoid tissue (observed in the thymus, spleen and lymph nodes) and mortality (RIVM, 2013; OECD, 2007; WHO, 2001).

Reproductive/Developmental Toxicity

A continuum of biologically relevant reproductive/developmental effects have been reported following NMP exposure (e.g., decreased fetal and pup body weight, delayed ossification, skeletal malformations

and increased fetal and pup mortality). EPA previously identified reproductive/developmental effects as sensitive endpoints for evaluating the human health risks associated with NMP exposure U.S. EPA (2015).

2.4.2.2 Genotoxicity and Cancer Hazards

NMP is not mutagenic, based on results from bacterial and mammalian *in vitro* tests and *in vivo* systems and is not considered to be carcinogenic (RIVM, 2013; OECD, 2007; WHO, 2001).

Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity and cancer hazards during risk evaluation.

2.4.2.3 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation" by EPA. TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." In developing the hazard assessment, EPA will analyze available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s). In the previous risk assessment (U.S. EPA, 2015), EPA identified young children and pregnant women as potentially susceptible subpopulations.

2.5 Conceptual Models

EPA risk assessment guidance (U.S. EPA, 2014, 1998c), defines problem formulation as the part of the risk assessment framework that identifies the major factors to be considered in the assessment. It draws from the regulatory, decision-making and policy context of the assessment and informs the assessment's technical approach.

A conceptual model describes the actual or predicted relationships between the chemical substance and receptors, either human or environmental. These conceptual models are integrated depictions of the conditions of use, exposures (pathways and routes), hazards and receptors. The initial conceptual models describing the scope of the assessment for NMP, have been refined during problem formulation. The changes to the conceptual models in this problem formulation are described along with the rationales.

In this section EPA outlines those pathways that will be included and further analyzed in the risk evaluation; will be included but will not be further analyzed in risk evaluation; and will not be included in the TSCA risk evaluation; and the underlying rationale for these decisions.

EPA determined as part of problem formulation that it is not necessary to conduct further analysis on certain exposure pathways that were identified in the NMP Scope Document (EPA-HQ-OPPT-2016-0743) and that remain in the risk evaluation. Each risk evaluation will be "fit-for-purpose," meaning not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without extensive or quantitative risk evaluations 82 FR 33726, 33734, 33739 (July 20, 2017).

As part of this problem formulation, EPA identified exposure pathways under regulatory programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage

exposures and for which long-standing regulatory and analytical processes already exist, i.e., the Safe Drinking Water Act (SDWA) and the Resource Conservation and Recovery Act (RCRA). OPPT worked closely with the offices within EPA that administer and implement the regulatory programs under these statutes. In some cases, EPA has determined that chemicals present in various media pathways (i.e., air, water, land) fall under the jurisdiction of existing regulatory programs and associated analytical processes carried out under other EPA-administered statutes and have been assessed and effectively managed under those programs. EPA believes the TSCA risk evaluation should generally focus on those exposure pathways associated with TSCA conditions of use that are not adequately assessed and effectively managed under the regulatory regimes discussed above because these pathways are likely to represent the greatest areas of risk concern. As a result, EPA does not expect to include in the risk evaluation certain exposure pathways identified in the NMP scope document.

2.5.1 Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

The revised conceptual model (Figure 2-2) describes the pathways of exposure from industrial and commercial activities and uses of NMP that EPA expects to include in the risk evaluation. There is a potential for inhalation and dermal exposure to workers during manufacturing, processing, use and disposal of NMP. Inhalation and vapor-through-skin exposures are also possible for occupational non-users, particularly with conditions of use that involve heating or spray application.

Dermal exposure is expected to be a major route of concern in occupational settings; however, there is a potential for inhalation exposure with some conditions of use that involve heating or spray application. EPA expects to evaluate dermal and inhalation risks to workers and occupational non-users exposed during manufacturing, processing, distribution, use and disposal of NMP.

Inhalation

EPA's previous assessment of NMP use in paint and coating removal identified inhalation as a route of concern for occupational exposure U.S. EPA (2015). NMP is well absorbed from the respiratory tract (Akesson and Paulsson, 1997), but has a low vapor pressure which effectively limits inhalation potential. Lung uptake is directly related to the NMP air concentration and duration of exposure. EPA expects that inhalation exposure may be significant for some conditions of use identified in Table 2-3, particularly those that involve heating or spray application. Incidental ingestion of inhaled NMP (vapor/mist/dust) will be considered as an inhalation exposure. EPA expects to further analyze inhalation exposures to workers and occupational non-users during risk evaluation.

Dermal

EPA's previous assessment identified dermal contact as a major route of concern for NMP U.S. EPA (2015). For workers, dermal exposures would be concurrent with inhalation exposures and NMP is well absorbed; therefore, dermal contact (e.g., liquid, vapor, mist, dust) is expected to significantly impact body burden (Bader et al., 2008; Keener et al., 2007). Because occupational non-users would not handle NMP directly, EPA does not expect to further analyze dermal exposure via liquid contact. During risk evaluation, EPA expects to further analyze dermal exposures to workers from skin contact with NMP (e.g., liquid, vapor, mist, dust) and vapor-through-skin contact in occupational non-users.

The Occupational Safety and Health Administration (OSHA) has not established regulatory exposure limits for NMP. The only recommended exposure limit identified is a non-regulatory limit established by the AIHA: a workplace environmental exposure level (WEEL) of 10 ppm as an 8-hr time weighted average (TWA), with the addition of a cautionary note addressing concerns for skin contact (AIHA,

2011). EPA expects to further analyze dermal exposure to workers and occupational non-users during risk evaluation.

Waste Handling, Treatment and Disposal

Figure 2-2 shows that waste handling, treatment and disposal is expected to lead to the same exposure pathways as other industrial and commercial activities and uses. The path leading from "Waste Handling, Treatment and Disposal" to "Hazards Potentially Associated with Acute and/or Chronic Exposures" was re-routed to accurately reflect the expected exposure pathway, route and receptors associated with the conditions of use identified for NMP.

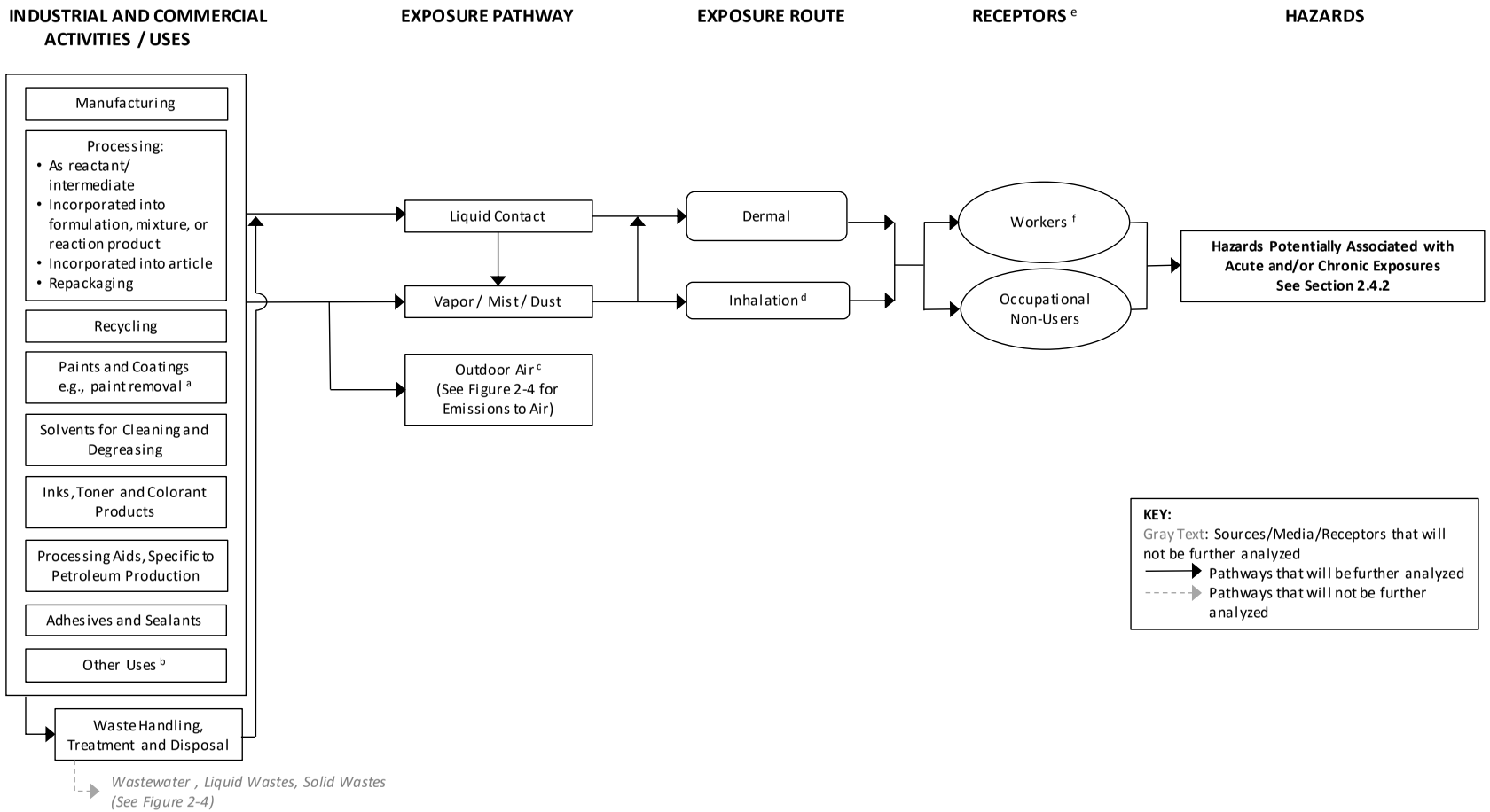


Figure 2-2. NMP Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

The exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of NMP.

[a] U.S. EPA (2015) assessed NMP use in paint removal; these uses will be considered during risk evaluation to ensure previous assessments are in alignment with the Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (40 CFR Part 702).

[b] Some products are used in both commercial and consumer applications. Additional uses of NMP are included in Table 2-3.

[c] Emissions to outdoor air include stack emissions and fugitive emissions such as fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections and open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

[d] Oral exposure via incidental ingestion of inhaled vapor/mist/dust will be considered as an inhalation exposure.

[e] Receptors include potentially exposed or susceptible subpopulations.

[f] When data and information are available to support the analysis, EPA expects to consider the effect that engineering controls and/or personal protective equipment have on occupational exposure levels.

2.5.2 Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

The revised conceptual model (Figure 2-3) illustrates the pathways of exposure resulting from NMP consumer uses that EPA expects to evaluate. In the (U.S. EPA, 2015) risk assessment, dermal and inhalation exposures were assessed as the most likely exposure routes; however, there is a potential for oral exposure under some conditions of use. It should be noted that consumers may purchase and use products primarily intended for commercial use.

Inhalation

As mentioned above, EPA/OPPT's 2015 assessment of NMP use in paint stripping identified inhalation as a route of concern U.S. EPA (2015). EPA expects inhalation exposure to be significant for some conditions of use identified in Table 2-3, particularly those that involve heating or spray application. Incidental ingestion of inhaled NMP (vapor/mist/dust) will be considered as an inhalation exposure. EPA expects to further analyze inhalation exposures to consumers and bystanders during risk evaluation.

Dermal

There is a potential for dermal exposure from use of consumer products that contain NMP. Dermal exposure may occur from vapor or mist deposition onto skin, or from direct contact with NMP liquid during use. Dermal exposure to liquid NMP could be concurrent with vapor-through-skin exposures for some conditions of use, particularly those that involve heating or spray application of products with a high NMP weight fraction. Bystanders will not have dermal contact with liquid NMP, but could have vapor-through-skin uptake.

Consumers and bystanders can have skin contact with NMP vapor concurrently with inhalation exposures. As noted for workers (see Section 2.5.1), lung uptake is impacted by the NMP weight fraction in liquid, the NMP vapor concentration in air and the duration and extent of dermal contact (i.e., surface area of exposed skin) with liquid and vapor forms of NMP. EPA expects to further analyze dermal exposure to consumers via direct contact with NMP-containing liquids and vapor-through-skin exposure to consumers and bystanders.

Oral

There is a potential for oral exposure to consumers from contact with NMP-containing products via hand-to-mouth activity. Mouthing behaviors may also be an important consideration, especially for children. The frequency and duration of these activities, as well as the NMP content in related products can impact exposure potential. EPA expects to further analyze consumer oral exposures that may result from hand-to-mouth activity and mouthing behaviors during use of formulations, products or other articles that contain NMP (e.g., toys, textiles).

Disposal

There is a potential for consumer exposure via oral, dermal and inhalation routes during disposal of NMP-containing products. Individuals may be exposed via contact with liquid or vapor forms of NMP when products are discarded. During risk evaluation, EPA expects to further analyze consumer exposures associated with the disposal of consumer products that contain NMP.

For each condition of use identified in Table 2-3, a determination was made as to whether each unique combination of exposure pathway, route, and receptor would be further analyzed during risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix C and Appendix E.

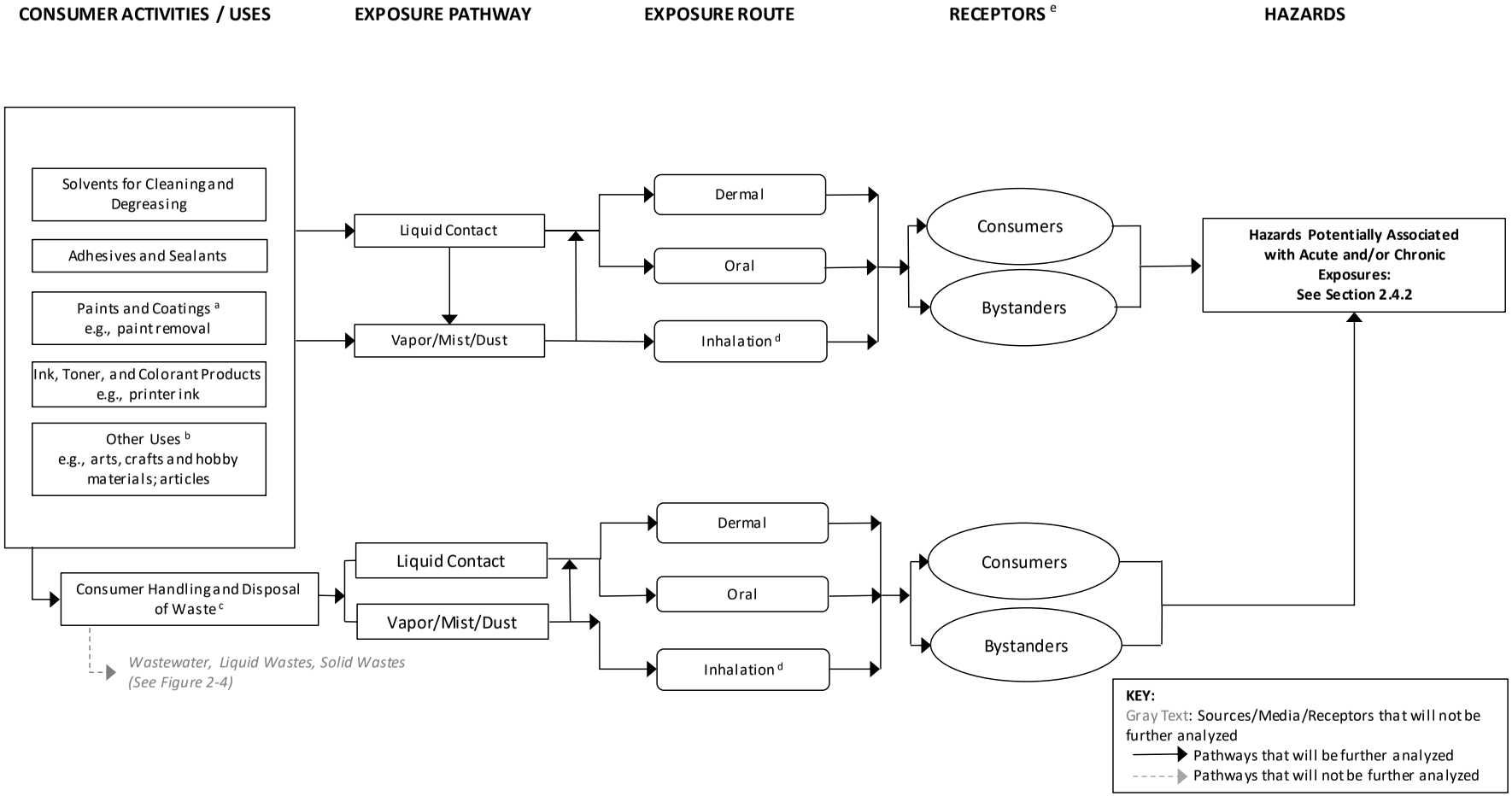


Figure 2-3. NMP Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of NMP.

[a] U.S. EPA (2015) assessed NMP use in paint and coating removal; these uses will be considered during risk evaluation to ensure previous assessments are in alignment with the Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (40 CFR Part 702).

[b] Some products are used in both commercial and consumer applications; additional uses of NMP are included in Table 2-3.

[c] Consumers may also be exposed while handling municipal wastes; however, the pathway is uncertain.

[d] Oral exposure via incidental ingestion of inhaled vapor/mist/dust will be considered as an inhalation exposure.

[e] Receptors include potentially exposed or susceptible subpopulations.

2.5.3 Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

The revised conceptual model (Figure 2-4) illustrates the exposure pathways anticipated for humans and other ecological receptors from environmental releases and waste streams associated with industrial and commercial use of NMP that EPA expects to include in the risk evaluation. The exposure pathways that EPA expects to include but not further analyze in the risk evaluation are described in Section 2.5.3.1 and shown in the conceptual model.

2.5.3.1 Pathways That EPA Expects to Include in Risk Evaluation but Not Further Analyze

EPA does not expect to further analyze environmental exposures to NMP.

Ambient Water Pathways

EPA does not plan to further analyze exposures to humans or ecological receptors including fish, aquatic invertebrates and algae from NMP releases to ambient surface water. Based on 2015 TRI reporting, an estimated 14,092 pounds of NMP was released to surface water from industrial and commercial sources (U.S. EPA, 2017b). Although NMP exhibits high water solubility, it is not expected to persist in surface waters because it readily biodegrades under aerobic conditions.

Environmental monitoring data were not identified for NMP; however, based on the estimated exposure concentrations (described in Section 2.3.4), and available ecological hazard information (summarized in Section 2.4.1), EPA does not plan to further analyze risks to aquatic organisms from NMP releases to surface water. A first-tier exposure analysis predicted surface water concentrations as high as 224 µg/L and 11 µg/L for the acute and chronic exposure scenarios, respectively based on reported TRI releases (summarized in Section 2.4.1). These values do not exceed the acute and chronic COCs for aquatic organisms (246 µg/L and 1,768 µg/L, respectively) indicating a low risk concern. This finding is supported by a recent ecological risk classification completed by Environment and Climate Change Canada which identified a low risk concern for NMP (ECCC, 2016).

EPA does not plan to further analyze exposures to humans that may result from NMP releases to ambient surface water. A first-tier analysis used to estimate NMP surface water concentrations based on the highest water releases reported in the 2015 TRI database showed that NMP levels in well water could be as high as 0.07 mg/kg/day. In the previous NMP risk assessment (U.S. EPA (2015), EPA identified a point of departure (POD) for chronic exposure in humans (48 mg/kg/day), which when compared to the estimated exposure concentration, resulted in a margin of exposure (MOE) that exceeded the benchmark MOE (675 versus 30, respectively). EPA also estimated oral and dermal exposure to NMP during showering/bathing. The calculated MOE, based on aggregate estimates of oral, inhalation and dermal exposure (338), exceeded the benchmark MOE (30), indicating a low risk concern.

Sediment Pathway

EPA does not plan to further analyze exposures to sediment-dwelling organisms during risk evaluation, as NMP is unlikely to accumulate in sediment. NMP is not expected to adsorb to sediment due to its water solubility (> 1000 g/L) and low partitioning to organic matter (log K_{oc} = 0.9). This is supported by EPISUITE fugacity model predictions which indicate limited partitioning to sediment (< 1%). No ecotoxicity studies were identified for sediment-dwelling organisms; however, the available hazard data indicate a low concern for NMP toxicity to plants and aquatic organisms. Because NMP toxicity to sediment-dwelling invertebrates is expected to be comparable to that of aquatic invertebrates and NMP

is unlikely to accumulate in sediment, a low risk concern is expected for this environmental compartment.

Land-Applied Biosolids Pathway

EPA does not plan to further analyze other land releases during risk evaluation, including those that may result from land application of biosolids. NMP exhibits high water solubility (1000 g/L) and limited potential for adsorption to organic matter (estimated log Koc = 0.9); therefore, land releases will ultimately partition to the aqueous phase (i.e., biosolids associated waste water and soil pore water) upon release into the environment. Because NMP readily biodegrades in environments with active microbial populations, NMP residues that remain following waste water treatment are not expected to persist. NMP concentrations in biosolids-associated water are expected to decrease, primarily via aerobic degradation, during transport, processing (including dewatering), handling, and land application of biosolids (which may include spraying).

Migration of NMP between ground water and surface water has not been documented, but may be mitigated by abiotic and biotic degradation in the water column. Overall, the NMP concentrations in surface water resulting from land application of biosolids are expected to be much less than those associated with direct release of wastewater treatment plant effluents to surface water. EPA's conservative assessment of this exposure scenario predicted NMP surface water concentrations that are well below the hazard benchmarks identified for humans and aquatic organisms (see Appendix C); therefore, this exposure pathway is not expected to present a risk concern.

Ambient Air Pathways

EPA does not plan to further analyze NMP air releases or associated exposures to terrestrial wildlife, as inhalation exposure and bioaccumulation potential are expected to be low (BCF = 3.16, BAF = 0.9; see Section 2.4). Negligible volatilization of NMP is expected from moist soil and wastewater. Because NMP exhibits low volatility and readily biodegrades under aerobic conditions (U.S. EPA (2015), the concentrations in ambient air are unlikely to reach levels that would present a risk concern for terrestrial organisms. This conclusion is supported by the ecological risk classification derived for NMP by Environment and Climate Change Canada, which identified a low ecological risk concern for NMP (ECCC, 2016).

EPA does not plan to further analyze human exposures that may result from inhalation of outdoor air containing NMP released from industrial and commercial facilities. A first-tier screening analysis was used to estimate the potential (near field) exposure to populations located downwind of facilities reporting the highest NMP air releases based on 2015 TRI data. Using EPA's SCREEN3 Model and the highest reported stack emissions, the estimated NMP concentration in ambient air was approximately 0.41 mg/m^3.

In the previous NMP assessment, EPA used data on NMP-induced decreases in fetal body weight as the basis for risk estimation. Benchmark dose modeling of internal dose estimates based on physiologically-based pharmacokinetic modelling was used to determine a POD (48 mg/kg/day) for estimating risks associated with chronic exposure in humans (U.S. EPA (2015). This POD was converted to an inhalation dose (based on a total dose of 3,840 mg/day, and 80 kg bodyweight). EPA's EFAST model uses a default breathing rate of 0.61 m^3/hour over a 24-hour period (14.6 m^3/day). Hence the inhalation POD is: (3,840 mg/day)/(14.6 m^3/day) = 263 mg/m^3 (24-hour TWA). EPA also expects to consider studies that have been published since this assessment, as identified in the literature search conducted by

the Agency (*NMP (CASRN 872-50-4) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0743).

During problem formulation, EPA assessed the risks associated with chronic NMP exposure by comparing the estimated concentration of NMP in ambient air (0.41 mg/m^3) to the POD for inhalation exposure (263 mg/m^3). This resulted in a margin of exposure (MOE) that exceeded the benchmark MOE (641 versus 30, respectively) indicating a low risk concern.

EPA acknowledges the possibility that NMP releases to ambient air may be wet deposited to soil and surface water; however, aerobic degradation and atmospheric dispersion are expected to limit the NMP air concentrations available to organisms that inhabit these compartments. As such, NMP air removal via wet deposition (from air to water or soil) is not expected to result in significant accumulation in these environmental compartments. This conclusion is supported by EPA's conservative assessment of NMP concentrations in air and surface water; the Tier 1 exposure estimates for these media do not indicate a concern for humans or other ecological receptors. The exposure pathways associated with NMP releases to ambient air will not be further analyzed during risk evaluation.

2.5.3.2 Pathways that EPA Does Not Plan to Include in the Risk Evaluation

Exposures to receptors (i.e., general population, terrestrial species) may occur from industrial and/or commercial uses, industrial releases to air, water or land, and other conditions of use. As described in Section 2.5, EPA does not expect to include in the risk evaluation pathways under programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist. These pathways are described below.

Drinking Water Pathway

EPA has regular analytical processes to identify and evaluate drinking water contaminants of potential regulatory concern for public water systems under the Safe Drinking Water Act (SDWA).

The Contaminant Candidate List (CCL) is a list of unregulated contaminants that are known or anticipated to occur in public water systems and that may require regulation. EPA must publish a CCL and make Regulatory Determinations to regulate at least five CCL contaminants every 5 years. To regulate a contaminant, EPA must conclude the contaminant may have adverse health effects, occurs or is substantially likely to occur in public water systems at a level of concern and that regulation, in the sole judgement of the Administrator, presents a meaningful opportunity for health risk reduction.

NMP is listed on EPA's fourth CCL. NMP is on the CCL because EPA's Office of Water concluded that based on occurrence and health information the chemical is known or anticipated to occur in public water systems and may require regulation. Based on TRI information, the Agency concluded that NMP may occur in public water systems. Once contaminants have been placed on the CCL, EPA identifies if there are any additional data needs, including gaps in occurrence data for evaluation under Regulatory Determination; if sufficient occurrence data is lacking, the contaminant may be considered for monitoring under the Unregulated Contaminant Monitoring Rule. Hence, because the drinking water exposure pathway for NMP is being addressed under the regular analytical processes used to identify and evaluate drinking water contaminants of potential regulatory concern for public water systems under SDWA, EPA does not expect to include this pathway in the risk evaluation for NMP under TSCA. EPA's Office of Water and Office of Pollution Prevention and Toxics will continue to work together providing understanding and analysis of the SDWA regulatory analytical processes for public water

systems and to exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA.

Disposal Pathways

The general standard in RCRA section 3004(a) for the technical criteria that govern the management (treatment, storage, and disposal) of hazardous waste (i.e., Subtitle C) are those "necessary to protect human health and the environment," RCRA 3004(a). The regulatory criteria for identifying "characteristic" hazardous wastes and for "listing" a waste as hazardous also relate solely to the potential risks to human health or the environment. 40 C.F.R. §§ 261.11, 261.21-261.24. RCRA statutory criteria for identifying hazardous wastes require EPA to "tak[e] into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics." Subtitle C controls cover not only hazardous wastes that are landfilled, but also hazardous wastes that are incinerated (subject to joint control under RCRA Subtitle C and the Clean Air Act (CAA) hazardous waste combustion maximum achievable control technology) or injected underground into Class I hazardous waste wells (subject to joint control under Subtitle C and SDWA).

EPA does not expect to include emissions to ambient air from municipal and industrial waste incineration and energy recovery units in the risk evaluation, as they are regulated under section 129 of the Clean Air Act. CAA section 129 requires EPA to review and, if necessary, add provisions to ensure the standards adequately protect public health and the environment. Thus, combustion by-products from incineration treatment of NMP wastes (approximately 6 million lbs) would be subject to these regulations, as would NMP burned for energy recovery (7.6 million lbs).

EPA does not expect to consider on-site NMP land releases that are disposed via underground injection in the risk evaluation. Most of the on-site land disposal reported for NMP in the 2015 TRI was to Class I underground injection wells (approximately 3.6 million pounds), with no reported environmental releases via underground injection to Class II-VI wells (U.S. EPA, 2017b). Environmental disposal of NMP via injection into Class I wells is managed and prevented from further environmental releases by RCRA and SDWA regulations. Therefore, disposal of NMP via underground injection is not likely to result in environmental and general population exposures.

EPA does not plan to consider on-site land releases that go to RCRA Subtitle C hazardous waste landfills during risk evaluation. Based on the 2015 TRI data, approximately 93,217 pounds of NMP were transferred to RCRA Subtitle C landfills; smaller amounts (approximately 25,648 pounds) were characterized as "other" land disposal and off-site land treatment (approximately 330 pounds) (U.S. EPA, 2017b). Design standards for Subtitle C landfills require double liner, double leachate collection and removal systems, leak detection system, run on, runoff, and wind dispersal controls, and a construction quality assurance program. They are also subject to closure and post-closure care requirements including installing and maintaining a final cover, continuing operation of the leachate collection and removal system until leachate is no longer detected, maintaining and monitoring the leak detection and groundwater monitoring system. Bulk liquids may not be disposed in Subtitle C landfills. Subtitle C landfill operators are required to implement an analysis and testing program to ensure adequate knowledge of waste being managed and to train personnel on routine and emergency operations at the facility. Hazardous waste being disposed in Subtitle C landfills must also meet RCRA waste treatment standards before disposal. Given these controls, general population exposure to NMP from Subtitle C landfill leachate is not expected to be a significant exposure pathway.

EPA does not expect to include releases to land from RCRA Subtitle D municipal solid waste (MSW) landfills or exposures to the general population or terrestrial species from such releases in the risk evaluation. While permitted and managed by individual states, MSW landfills are required by federal regulations to implement some of the same requirements as Subtitle C landfills. MSW landfills must have a liner system with leachate collection and conduct groundwater monitoring and corrective action when releases are detected. MSW landfills are also subject to closure and post-closure care requirements, as well as providing financial assurance for funding of any needed corrective actions. MSW landfills have been designed to allow for the small amounts of hazardous waste generated by households and very small quantity waste generators (< 220 pounds per month). Bulk liquids, such as free solvent, may not be disposed of in MSW landfills.

EPA does not expect to consider on-site releases to land from industrial non-hazardous waste and construction/demolition waste landfills in the NMP risk evaluation. Industrial non-hazardous and construction/demolition waste landfills are primarily regulated under state regulatory programs. States must also implement limited federal regulatory requirements for siting, groundwater monitoring and corrective action and a prohibition on open dumping and disposal of bulk liquids. States may also establish additional requirements such as for liners, post-closure and financial assurance, but are not required to do so. Therefore, EPA does not expect to include this exposure pathway in the risk evaluation.

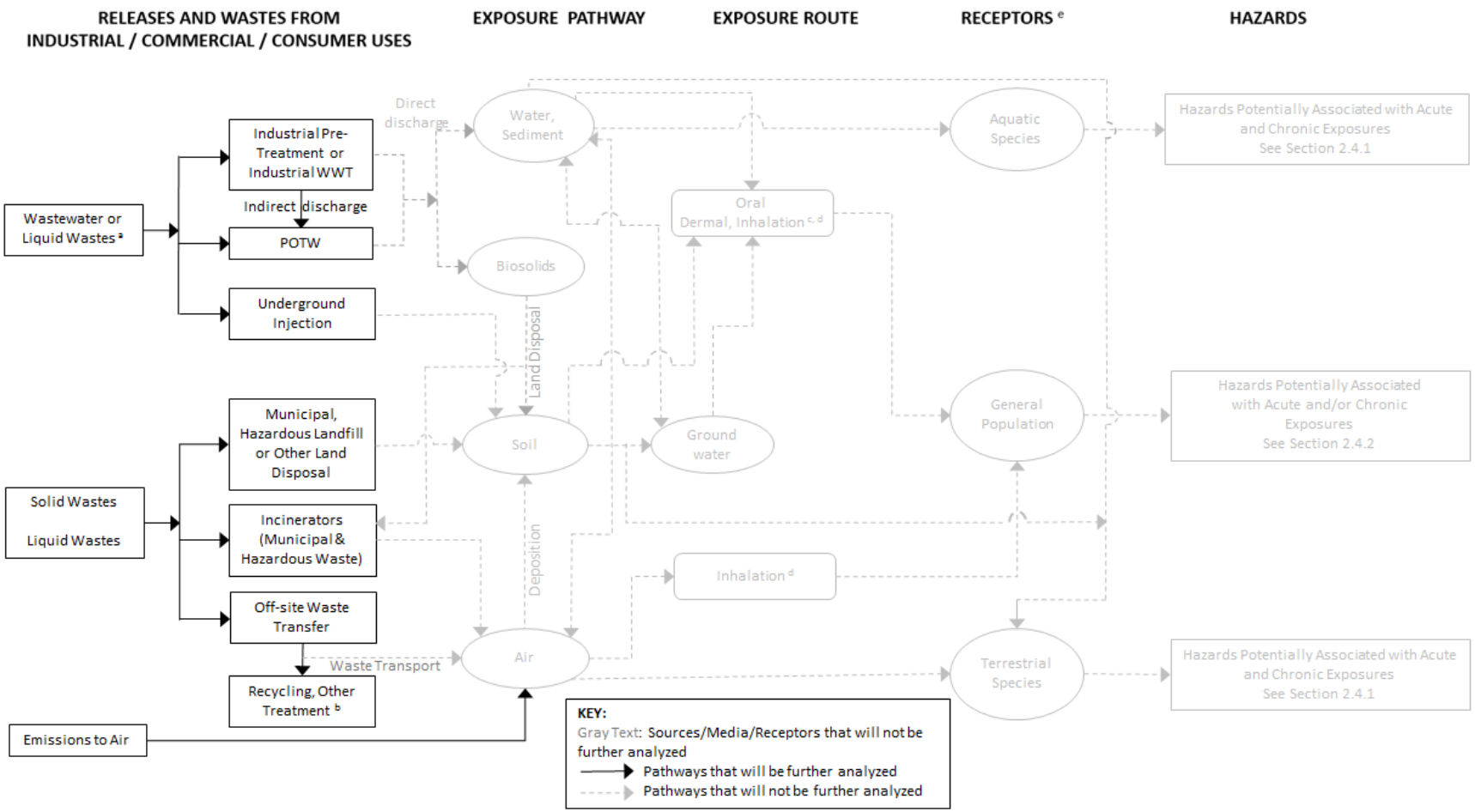


Figure 2-4. NMP Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of NMP.

[a] Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW (i.e., down the drain). Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.

[b] Additional releases may occur from recycling and other waste treatment.

[c] Volatilization from or liquid contact with drinking/tap water in the home during showering, bathing and washing represents another potential exposure pathway.

[d] Presence of mist is unlikely; inhalation and oral exposure are expected to be negligible.

[e] Receptors include potentially exposed or susceptible subpopulations.

2.6 Analysis Plan

The analysis plan presented in this problem formulation is a refinement of the initial analysis plan published in the *Scope of the Risk Evaluation for NMP* (U.S. EPA, 2017a).

The analysis plan outlined here is based on the conditions of use identified for NMP, as described in Section 2.2 of this problem formulation. EPA is implementing systematic review approaches to identify, select, assess, integrate and summarize the findings of studies supporting the TSCA risk evaluation. The analytical approaches and considerations in the analysis plan are used to frame the scope of the systematic review activities for this assessment. The supplemental document, *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018), provides additional information about criteria and methods that have been and will be applied to the first 10 chemical risk evaluations.

While EPA has conducted a search for reasonably available information from public sources as described in the *Scope of the Risk Evaluation for NMP* (U.S. EPA, 2017a), EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for refining conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations during the risk evaluation. EPA will continue to consider new information submitted by the public.

During risk evaluation, EPA will rely on the comprehensive literature results [*NMP (CASRN 872-50-4) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0743], or supplemental literature searches to address specific questions. Further, EPA may consider any relevant CBI in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure. The analysis plan is based on EPA's knowledge of NMP to date, which includes partial, but not complete review of identified literature. If additional data or approaches become available, EPA may refine its analysis plan based on this information.

2.6.1 Exposure

Based on their physical-chemical properties, expected sources, and transport and transformation within the outdoor and indoor environment chemical substances are more likely to be present in some media and less likely to be present in others. Media-specific levels will vary based on the chemical substance of interest. For most chemical substances, level(s) can be characterized through a combination of available monitoring data and modeling approaches.

2.6.1.1 Environmental Releases

EPA expects to consider and analyze releases to relevant environmental media as follows:

1) Review reasonably available published literature or information on processes and activities associated with NMP conditions of use to evaluate the types of releases and wastes generated. EPA has reviewed some key data sources containing information on processes and activities resulting in releases. EPA will continue to review potentially relevant data sources identified in Appendix B during risk evaluation.
2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data collected under the TRI program). EPA has reviewed key data sources including TRI; this data is summarized in Section 2.3.2 above. EPA will continue to review relevant data sources during risk evaluation. EPA will match identified data to applicable conditions of use and identify data gaps where no data are found for specific conditions of use.

EPA will attempt to address data gaps identified as described in steps 3 and 4 below by considering potential surrogate data and models.

3) Review measured or estimated release data for surrogate chemicals that have similar uses, volatility, and physical-chemical properties. Data for solvents that are used in the same types of applications may be considered as surrogate data for NMP. Perchloroethylene, dimethylformamide and NMP are used in paints, coatings, adhesives, sealants, and cleaning formulations. In addition, NMP is sometimes used as a replacement for methylene chloride in some paint removal use applications. EPA will review the literature sources identified and if surrogate data are found, EPA will match these data to applicable conditions of use to determine their suitability for filling data gaps. EPA will evaluate the utility of surrogate data to fill data gaps where uses of NMP and other solvents align. If surrogate data are used, EPA normally converts air concentrations using the ratio of the vapor pressures of the two chemicals.

4) Understand and consider regulatory limits that may inform estimation of environmental releases. EPA has identified information from various EPA statutes (including, for example, regulatory limits, reporting thresholds or disposal requirements) that may be relevant to release estimation. EPA will further consider relevant regulatory requirements in estimating releases during risk evaluation. While NMP is not a hazardous air pollutant regulated under the Clean Air Act, some related rules may provide relevant information on sectors that use NMP. For example, the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Paint Stripping and Miscellaneous Surface Coating Operations (40 CFR Part 63, Subpart HHHHHH) may provide useful information on industry sectors that use solvents (including NMP) for paint removal and surface coating applications.

5) Review and determine the applicability of the Organisation for Economic Cooperation and Development (OECD) Emission Scenario Documents (ESD) and EPA Generic Scenarios to estimation of environmental releases. Potentially relevant OECD ESDs and EPA Generic Scenarios (GS) have been identified that correspond to some conditions of use. For example, the ESD on Industrial Use of Adhesives for Substrate Bonding, the ESD on the Coating Industry (paints, lacquers and varnishes), and the GS on Application of Agricultural Pesticides are some of the ESDs and GSs that EPA may use to assess potential releases. EPA will need to critically review the GSs and ESDs to determine their applicability to the conditions of use assessed. EPA was not able to identify ESDs or GSs corresponding to several conditions of use, including the manufacture and import of NMP, use of NMP in soldering materials and use of NMP in petrochemical purifications. EPA will perform additional targeted research to understand those conditions of use which may inform identification of release scenarios. EPA may also need to perform targeted research for applicable models and associated parameters that EPA may use to estimate releases for specific conditions of use. If ESDs and GSs are not available to fill data gaps, other methods may be considered, including existing emission factors, such as those from EPA AP-42, to estimate environmental releases of NMP to air from various conditions of use.

6) Map or group condition(s) of use to release assessment scenario(s). EPA has identified release scenarios and mapped them to some conditions of use. For example, some scenario groupings include Contractor Adhesive Removal and Industrial Spray Application of Lacquers, Paints, and Coatings. EPA grouped similar conditions of use (based on factors including process equipment and handling, release sources and usage rates of NMP and formulations containing NMP, or professional judgement) into scenario groupings but may further refine these groupings as

additional information becomes available during risk evaluation. EPA was not able to identify release scenarios corresponding to several conditions of use due to a lack of general knowledge of those conditions of use. EPA will perform additional targeted research to understand those uses which may inform identification of release scenarios.

Evaluate the weight of evidence for environmental release data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.1.2 Environmental Fate

EPA expects to consider and analyze fate and transport in environmental media as follows:

1) Review reasonably available measured or estimated environmental fate endpoint data collected through the literature search.

   A general overview of persistence and bioaccumulation was presented in the TSCA Work Plan Chemical Risk Assessment of N-Methylpyrrolidone: Paint Removal Use CASRN 872-50-4 (U.S. EPA, 2015). Key environmental fate characteristics were included in the *Scope of the Risk Evaluation for N-Methylpyrrolidone* (U.S. EPA, 2017a) and in previous assessments of NMP, including those conducted by EPA's Office of Pesticide Programs (U.S. EPA, 2015), US California Office of Environmental Health Hazard Assessment (OEHHA, 2003), Australia Department of Health, National Industrial Chemicals Notification and Assessment Scheme (Australian Government Department of Health, 2016), Environment Canada, Health Canada (EC/HC, 2017), and European Commission, Scientific Committee on Occupational Exposure Limits (EC, 2016). These information sources will be used as a starting point for the environmental fate assessment. Other sources that will be consulted include those that are identified through the systematic review process. Studies will be evaluated using the evaluation strategies laid out in the supplemental document, *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

   If measured values are not available (this will be determined during systematic review), chemical properties will be estimated using EPI Suite, SPARC and other chemical parameter estimation models. Estimated fate properties will be reviewed for applicability and quality.

2) Using measured environmental fate data and/or environmental fate modeling, determine the influence of environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on pathways and routes of exposure for human and environmental receptors.

   Measured fate data including atmospheric photolysis rates, hydrolysis, and aerobic and anaerobic biodegradation rates, along with physical-chemical properties and models such as the EPI Suite™ STP model (which estimates removal during wastewater treatment due to adsorption to sludge and volatilization to air), will be used to characterize the movement of NMP within and among environmental media and the persistence of NMP within specific media.

3) Evaluate the weight of the evidence of environmental fate data.

2.6.1.3 Environmental Exposures

EPA does not plan to further analyze environmental exposures to NMP, based on the rationale described in Section 2.3.4.

2.6.1.4 Occupational Exposures

EPA expects to consider and analyze exposures to workers and occupational non-users as follows:

1) Review reasonably available exposure monitoring data for specific condition(s) of use. Exposure data to be reviewed may include workplace monitoring data collected by government agencies such as OSHA and the National Institute of Occupational Safety and Health (NIOSH), and monitoring data found in published literature. These workplace monitoring data may include personal exposure monitoring data and area monitoring data (e.g., stationary sampling). Data, information, and studies will be evaluated using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018). EPA has reviewed available monitoring data collected by OSHA (see the summary in Appendix 2.6.3B.2) and will match these data to applicable conditions of use. EPA has also identified additional data sources that may contain relevant monitoring data for the various conditions of use. EPA will review the sources identified in Appendix B and extract relevant data for consideration and analysis during risk evaluation. Data gaps will be identified where no data are found for specific conditions of use. EPA will attempt to address data gaps identified as described in steps 2 and 3 below. Where possible, job descriptions may be useful in distinguishing exposures to different subpopulations within a specific condition of use.

2) Review reasonably available exposure data for surrogate chemicals that have uses, volatility and physical-chemical properties that are comparable to NMP. EPA will review literature sources identified and if surrogate data are found, these data will be matched to applicable conditions of use for potentially filling data gaps. For several uses (e.g., use as solvent), EPA believes that dimethylformamide may share the same or similar conditions of use and may be considered as a surrogate for NMP.

3) For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels. Models may be generic, broadly applicable models or may be specific to conditions of use (e.g., some OECD Emission Scenario Documents (ESDs) and U.S. EPA Generic Scenarios (GSs) may be identified as potentially mapping to some conditions of use). EPA has identified potentially relevant OECD ESDs and EPA GSs that correspond to some conditions of use. For example, the ESD on Industrial Use of Adhesives for Substrate Bonding, the ESD on Metal Finishing and the GS on the Manufacture and Use of Printing Inks are some of the ESDs and GSs that EPA may use to estimate occupational exposures. EPA will need to critically review these scenarios to determine their applicability to the conditions of use identified for NMP. EPA was not able to identify ESDs or GSs corresponding to several conditions of use, including recycling of NMP and solvent mixtures containing NMP, processing and formulation of NMP into industrial, commercial and consumer products, use of NMP in paints and coatings, and use of NMP in petrochemical purifications. EPA will perform additional targeted research to understand those conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted research to identify applicable models that EPA may use to estimate exposures for specific conditions of use. If any models are identified as applicable, EPA will search for appropriate model parameter data (as described in step 4 below). If parameter data can be located or assumed, exposure estimates generated from these models may be used for potentially filling data gaps.

4) Review reasonably available information that may be used in developing, adapting or applying exposure models to the risk evaluation. This step will be performed after Steps 2 and 3 above. Based on information developed from Steps 2 and 3, EPA will evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding exposure scenarios). EPA previously assessed dermal and inhalation exposure to workers and occupational non-users during NMP use in paint and graffiti removal (U.S. EPA, 2015). Inputs to the PBPK model were developed from air monitoring data and dermal parameter data and assumptions for workers. EPA will utilize results from the previous assessment during risk evaluation. EPA may develop models for other conditions of use, where appropriate.

5) Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios. EPA will review potentially relevant data sources on engineering controls and personal protective equipment as identified in Table_Apx B-7 and determine their applicability for incorporation into specific exposure scenarios during risk evaluation. OSHA has not established any occupational exposure limits for NMP; however, AIHA has adopted a recommended workplace environmental exposure level (WEEL) of 10 ppm based on a time-weighted average (TWA) over an 8-hour workday. EPA will consider the influence of the recommended exposure guidelines in its occupational exposure assessment.

6) Map or group each condition of use to occupational exposure assessment scenario(s). EPA has identified occupational exposure scenarios and mapped them to conditions of use. For example, one scenario grouping is the Industrial Spray Application of Lacquers, Paints, and Coatings, where products containing NMP are applied to substrates via spraying methods in an industrial setting. EPA grouped similar conditions of use (e.g., based on factors including process equipment and handling, usage rates and NMP content of product formulations, exposure/release sources, or professional judgement) into scenario groupings but may further refine these groupings as additional information is identified during risk evaluation. EPA was not able to identify occupational exposure scenarios corresponding to several conditions of use due to a lack of general understanding of those conditions of use. For example, EPA has not identified information related to exposure during the use of NMP in petrochemical purifications. EPA will perform targeted research to understand those uses which may inform identification and refinement of occupational exposure scenarios.

7) Evaluate the weight of evidence of occupational exposure data. The data integration strategy will be designed to be “fit-for-purpose”. EPA will use systematic review methods to assemble the relevant data and evaluate data quality, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.1.5 Consumer Exposures

EPA expects to consider and analyze exposures to consumers as follows:

1) Refine and finalize exposure scenarios for consumers by considering unique combinations of sources (consumer uses), exposure pathways, exposure settings, exposed populations and exposure routes. For NMP, the following are noteworthy considerations in constructing exposure scenarios for consumers:
   - reasonably available data sources, including those that provide information on NMP content in manufactured, processed, used, or recycled consumer products and articles, including

temporal trends associated with such data; an example of an information source with product information (e.g., NMP content) is the CDC Household Products Database.

- information characterizing use patterns for consumer products that contain NMP including how the product is used, the amount of product used, the frequency and duration of use and specific characteristics regarding the room in which the product is used;
- the exposure setting and route of exposure for potentially exposed populations, including susceptible subpopulations that may be exposed via consumer product use, including those who use commercial products that contain higher concentrations of NMP, or those who may use NMP-containing products more frequently;
- information characterizing the potential for NMP release from products and articles into the indoor environment through diffusion from materials to air, physical abrasion, or direct transfer to dust;
- EPA will map products according to their NMP content, use patterns and exposure routes, including potentially exposed or susceptible subpopulations to develop exposure scenarios.

2) Evaluate consumer exposures to products and articles containing NMP. The 2015 NMP Risk Assessment for Paint Removal Use provides an in-depth characterization of paint removal products, including the NMP content, use patterns and associated exposures that may occur via their use. During risk evaluation, EPA will consider these paint removal uses along with other consumer uses to conduct a first-tier exposure analysis. The results of this analysis will then be used to determine which consumer use scenarios may need a more refined exposure assessment. In addition to the comparison of consumer exposure scenarios to each other, the associated exposure estimates for each scenario will also be compared to the hazard benchmarks identified for dermal and inhalation exposure. Based on the results of this evaluation, EPA may consider a subset of consumer use scenarios for a more extensive analysis.

3) Evaluate the indoor exposure pathways based on available data. Indoor exposures are likely to be higher than outdoor exposures and may include a potential for oral, dermal and inhalation contact. Data sources associated with these pathways have not been comprehensively evaluated; however, quantitative comparisons across exposure pathways will be considered during risk evaluation.

4) Review existing consumer exposure models that may be applicable in estimating indoor air concentrations (near field and far field) for the user and in estimating dermal exposure to consumer users. Determine the applicability of the identified models for use in a quantitative exposure assessment.

5) Review reasonably available consumer product-specific sources to determine how exposure estimates compare with each other and with indoor monitoring data on NMP levels in dust or indoor air. EPA will review the available empirical data for use in developing, adapting or applying exposure models such as the Consumer Exposure Model (CEM) to the risk evaluation. The CEM parameters used in EPA's 2015 assessment of NMP use in paint removal and will be reviewed to determine if they can be used to evaluate other NMP use scenarios.

6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if EPA's identification of potentially exposed or susceptible subpopulations need to be further refined. Possible considerations include:

- the characteristics of the user of the consumer product and the bystander(s) in the room, including for example, women of child bearing age and children.
- subpopulations who may have greater exposure due to the magnitude, frequency or duration of exposure as applicable to specific consumer products.

7) Evaluate the weight of evidence available for consumer exposure estimates based on different approaches.

2.6.1.6 General Population Exposures

EPA does not expect to include general population exposures in the risk evaluation for NMP. EPA has determined that the existing regulatory programs and associated analytical processes adequately assess and effectively manage the risks of NMP that may be present in various media pathways (e.g., air, water, land) for the general population. For these cases, EPA believes that the TSCA risk evaluation should focus not on those exposure pathways, but rather on exposure pathways associated with TSCA conditions of use that are not subject to those regulatory processes, because the latter pathways are likely to represent the greatest areas of concern to EPA.

2.6.2 Hazards (Effects)

2.6.2.1 Environmental Hazards

EPA's conservative screening analysis demonstrated a low risk concern for NMP based on currently available information (e.g., physical-chemical properties, fate characteristics and TRI-reported environmental releases). EPA does not expect to further analyze environmental hazards.

2.6.2.2 Human Health Hazards

EPA expects to consider and analyze human health hazards as follows:

1) Review reasonably available human health hazard data, including data from alternative test methods as needed (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; in vitro studies; systems biology).

   Human health studies will be evaluated using the evaluation strategies laid out in the supplemental document, *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). Human and animal data will be identified and included as described in the inclusion and exclusion criteria in Appendix G. EPA expects to prioritize the evaluation of mechanistic evidence. Specifically, EPA does not plan to evaluate mechanistic studies unless needed to clarify questions about associations between NMP and health effects and its relevance to humans. The *Applications of Systematic Review in TSCA Risk Evaluations* document describes the process of how studies will be evaluated using specific data evaluation criteria and a predetermined approach. Study results will be extracted and presented in evidence tables by hazard endpoint. EPA expects to evaluate relevant studies identified in the *TSCA Work Plan Chemical Risk Assessment on NMP use in Paint Stripping* U.S. EPA (2015). In addition, EPA intends to review studies that were captured in the comprehensive literature search conducted by the Agency for NMP [*NMP (CASRN 872-50-4) Bibliography: Supplemental File for the TSCA Scope Document,* (EPA-HQ-OPPT-2016-0743)], and supplemental literature searches to address specific questions. Further, EPA will consider any relevant CBI in a manner that protects the confidentiality of the information from public disclosure.

2) When evaluating available data, determine whether specific individual groups may have greater susceptibility to NMP hazard(s) than the general population.

3) Conduct hazard identification (the qualitative process of identifying human health hazard endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for all identified human health hazard endpoints.

   Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the data quality criteria described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). Studies meeting data quality criteria will be grouped by routes of exposure relevant to humans.

4) Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a). Dose-response analyses performed to support the *TSCA Work Plan Chemical Risk Assessment on NMP use in Paint Stripping* U.S. EPA (2015) may be used if the data meet data quality criteria and if additional information on the identified hazard endpoints or additional hazard endpoints would not alter this analysis.

5) Derive POD and conduct benchmark dose modeling when feasible based on the available data.

   Hazard data will be evaluated to determine the type of dose-response modeling that is applicable, if updates are needed. When modeling is feasible, a set of dose-response models that are consistent with a variety of underlying biological processes will be applied to empirically model the dose-response relationships within the range of the observed data consistent with EPA's *Benchmark Dose Technical Guidance Document*. When dose-response modeling is not feasible, NOAEL or LOAEL values will be identified.

6) Consider the route(s) of exposure (oral, inhalation, dermal), available exposure data and modeling approaches to integrate exposure and hazard assessment.

7) Evaluate the weight of evidence based on human health hazard data.

   EPA will rely on the weight of scientific evidence when evaluating and integrating human health hazard data. The strategy will be designed to be "fit-for-purpose". EPA will use systematic review methods to assemble the relevant data, evaluate for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.3 Risk Characterization

Risk characterization is an integral component of the risk assessment process for both ecological and human health risks. EPA will derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000). As defined in EPA's Risk Characterization Policy, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers." Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of risk but also the strengths and limitations of the assessment and a description of how others have assessed the risk into an integrated picture.

Risk characterization at EPA assumes different levels of complexity depending on the nature of the risk being characterized. The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or

information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent and reasonable (U.S. EPA, 2000). EPA will also present information in this section consistent with approaches described in the *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726). For instance, in the risk characterization summary, EPA will further carry out the obligations under TSCA section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review. EPA will also be guided by EPA's *Information Quality Guidelines* (U.S. EPA, 2002) which provide guidance for presenting risk information. Consistent with those guidelines, in the risk characterization, EPA will identify: (1) Each population addressed by an estimate of applicable risk effects; (2) the expected risk or central estimate of risk for the potentially exposed or susceptible subpopulations affected; (3) each appropriate upper-bound or lower-bound estimate of risk; (4) each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) peer reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

REFERENCES

AIHA (American Industrial Hygiene Association). (2011). WEEL® (Workplace Environmental Exposure Limit) Values (2011) [Standard]. Fairfax, VA: American Industrial Hygiene Association Guideline Foundation. https://www.aiha.org/get-involved/AIHAGuidelineFoundation/WEELs/Documents/2011WEELValues.pdf.

Akesson, B; Paulsson, K. (1997). Experimental exposure of male volunteers to N-methyl-2-pyrrolidone (NMP): acute effects and pharmacokinetics of NMP in plasma and urine. Occup Environ Med. 54(4): 236-240.

Anderson, LR; Liu, K, ou-Chang. (2000). Pyrrole and pyrrole derivatives. In Kirk-Othmer Encyclopedia of Chemical Technology (4th ed.). New York, NY: John Wiley & Sons. http://dx.doi.org/10.1002/0471238961.1625181801140405.a01 ; http://onlinelibrary.wiley.com/doi/10.1002/0471238961.1625181801140405.a01/abstract.

Ashford, R. (1994). Ashford's dictionary of industrial chemicals: Properties, production, uses. London: Wavelength.

ATSDR (Agency for Toxic Substances and Disease Registry). (2015). Health consultation: Review of air quality data: Intel Corporation – New Mexico facility: Rio Rancho, Sandoval County, New Mexico: EPA facility ID: NMD000609339, Part 2. Atlanta, GA: U.S. Department of Health and Human Services.

Australian Government Department of Health. (2016). Human health tier III assessment for 1-methyl-2-pyrrolidinone (pp. 25). Canberra, Australia. https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-iii-human-health/2-pyrrolidinone,-1-methyl-.

Bader, M; Rosenberger, W; Rebe, T; Keener, SA; Brock, TH; Hemmerling, HJ; Wrbitzky, R. (2006). Ambient monitoring and biomonitoring of workers exposed to N-methyl-2-pyrrolidone in an industrial facility. Int Arch Occup Environ Health. 79(5): 357-364. http://dx.doi.org/10.1007/s00420-005-0065-4.

Bader, M; Wrbitzky, R; Blaszkewicz, M; Schäper, M; van Thriel, C. (2008). Human volunteer study on the inhalational and dermal absorption of N-methyl-2-pyrrolidone (NMP) from the vapour phase. Arch Toxicol. 82(1): 13-20. http://dx.doi.org/10.1007/s00204-007-0230-5.

BASF. (1983). Unpublished data, study No. 83/112, 31 Aug 1983. BASF

BASF. (1986). Study No. 85/289, 05 Feb 1986 (unpublished).

BASF. (1990). Technical information: N-methylpyrrolidone handling and storage. Parsippany, NJ. http://infohouse.p2ric.org/ref/30/29008.pdf.

BASF. (1993). Modification of a vapor degreasing machine for immersion cleaning use N-methylpyrrolidone. Parsippany, NJ. http://infohouse.p2ric.org/ref/25/24025.pdf.

BASF. (1998). N-methylpyrrolidone(NMP): Biodegradability. Parsippany, NJ. http://infohouse.p2ric.org/ref/27/26726.pdf.

BASF AG. (2001). Unpublished study, project No. 00/0969/51/1, 25 Jul 2001. In Experimental Toxicology and Ecology. ((as cited in OECD, 2007)). BASF AG.

BPI (Bond Polymers International). (2017). NMP free water borne polyurethane dispersions [Website]. http://davyprotech.com/what-we-do/licensed-processes-and-core-technologies/licensed-processes/nmp/specification/.

Chemistry Industry Association of Canada. (2017a). All substances emissions for 2011 and projections for 2014. Ottawa, Canada. http://canadianchemistry.ca/library/docs/Total%20Emissions%202011%20with%20issues-Final%20Eng.pdf.

Chemistry Industry Association of Canada. (2017b). All substances emissions for 2012 and projections for 2015. Ottawa, Canada. http://www.canadianchemistry.ca/library/docs/Total%20emissions%202012.pdf.

Daniel, C. (2008). Materials and processing for lithium-ion batteries. J O M. 60(9): 43-48. http://dx.doi.org/10.1007/s11837-008-0116-x.
Danish EPA (Danish Environmental Protection Agency). (2015). List of Undesirable Substances (LOUS): Survey of 1-methyl-2-pyrrolidone. (1715). http://mst.dk/service/publikationer/publikationsarkiv/2015/jul/survey-of-1-methyl-2-pyrrolidone-nmp/.
Daubert, TE; Danner, RP. (1989). Physical and thermodynamic properties of pure chemicals: Data compilation. Washington, DC: Taylor & Francis.
Doherty, MF; Knapp, JP. (2004). Distillation, azeotropic, and extractive. In Kirk-Othmer Encyclopedia of Chemical Technology (4th ed.). New York, NY: John Wiley & Sons. http://onlinelibrary.wiley.com/doi/10.1002/0471238961.0409192004150805.a01.pub2/abstract.
EC (European Commission). (2004a). Effectiveness of vapour retardants in reducing risks to human health from paint strippers containing dichloromethane. Brussels, Belgium. http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_006.pdf.
EC (European Commission). (2004b). Effectiveness of vapour retardants in reducing risks to human health from paint strippers containing dichloromethane. Final report. http://ec.europa.eu/enterprise/sectors/chemicals/files/studies/etvaread-paint_stripper_dcm_en.pdf.
EC (European Commission). (2007a). Impact assessment of potential restrictions on the marketing and use of dichloromethane in paint strippers. Final report. http://bookshop.europa.eu/en/impact-assessment-of-potential-restrictions-on-the-marketing-and-use-of-dichloromethane-in-paint-strippers-pbNB0214154/.
EC (European Commission). (2007b). Recommendation from the scientific committee on occupational exposure limits for n-methyl-2-pyrrolidone. Brussels, Belgium. http://ec.europa.eu/social/BlobServlet?docId=3867&langId=en.
EC (European Commission). (2016). SCOEL/OPIN/2016-119 on N-Methyl-2-Pyrrolidone (NMP): Opinion from the Scientific Committee on Occupational Exposure Limits. Scientific Committee on Occupational Exposure Limits. http://files.chemicalwatch.com/2016-03-30_SCOEL-OPIN-2016-119.pdf.
EC/HC (Environment Canada and Health Canada). (2017). Draft Screening Assessment: 2-Pyrrolidinone, 1-methyl- (NMP) and 2-Pyrrolidinone, 1-ethyl- (NEP). Ministers of Environment and of Health. http://www.ec.gc.ca/ese-ees/65CB2E52-9213-4DF0-A3C1-9B0CD361CEB1/DRP-DSAR-NMP-NEP_EN-2017-02-01.pdf.
ECCC (Environment and Climate Change Canada). (2016). Science approach document: Ecological risk classification of organic substances. https://www.ec.gc.ca/ese-ees/A96E2E98-2A04-40C8-9EDC-08A6DFF235F7/CMP3%20ERC_EN.pdf.
ECHA (European Chemicals Agency). (2011). Annex XV dossier. Proposal for Identification of a Substance as a CMR Cat 1A or 1B, PBT, vPvB or a Substance of an Equivalent Level of Concern. http://echa.europa.eu/documents/10162/01e8a6d8-ba7a-474d-a640-49053005ec99.
ECHA (European Chemicals Agency). (2014a). Background document to the opinion on the annex XV dossier proposing restrictions on 1-methyl-2-pyrrolidone (NMP). Helsinki, Finland. http://echa.europa.eu/documents/10162/13641/background_document_nmp_dh001322-70_public_en.pdf.
ECHA. (2014b). REACH registration data [Database]. Retrieved from https://echa.europa.eu/registration-dossier/-/registered-dossier/15493/4/3
ECHA. (2017a). Uses as industrial sites: 1-Methyl-2-pyrrolidone. Helsinki, Finland. Retrieved from https://echa.europa.eu/registration-dossier/-/registered-dossier/15493/3/1/4#
ECHA. (2017b). Uses by professional workers: 1-Methyl-2-pyrrolidone. Helsinki, Finland. Retrieved from https://echa.europa.eu/registration-dossier/-/registered-dossier/15493/3/1/5#

ERG (Eastern Research Group Inc.). (2000). Preferred and alternative methods for estimating air emissions from paint and ink manufacturing facilities. Durham, NC: Emission Inventory Improvement Program. http://infohouse.p2ric.org/ref/17/ttn/volume02/ii08.pdf.
ERM. (2017). Life cycle assessment of used oil management. London, UK. http://www.api.org/~/media/Files/Certification/Engine-Oil-Diesel/Publications/LCA-of-Used-Oil-Mgmt-ERM-10012017.pdf.
European Chemicals Agency (ECHA). (2016). 1-methyl-2-pyrrolidone brief profile.
GAF (GAF Chemicals Corp.). (1979). Unpublished Study, Contract No. L1393-05, Aug 1976. In Aquatic Toxicology Laboratory. ((as cited in Verschuren, 2009 and OECD, 2007)). GAF Corp.
Gannon, RE, Manyik, R. M., Dietz, C. M., Sargent, H. B., Thribolet, R. O.; Schaffer, RP. (2003). Acetylene. In Kirk-Othmer Encyclopedia of Chemical Technology. New York, NY: John Wiley & Sons. http://dx.doi.org/10.1002/0471238961.0103052013011425.a01.pub2

http://onlinelibrary.wiley.com/doi/10.1002/0471238961.0103052013011425.a01.pub2/abstract.
Harreus, AL; Backes, R; Eichloer, J; Feuerhake, R; Jakel, C; Mahn, U; Pinkos, R; Vogelsang, R. (2011). 2-pyrrolidone. In Ullmann's Encyclopedia of Industrial Chemistry. [online]: John Wiley and Sons, Inc. http://onlinelibrary.wiley.com/doi/10.1002/14356007.a22_457.pub2/abstract.
Haufroid, V; Jaeger, VK; Jeggli, S; Eisenegger, R; Bernard, A; Friedli, D; Lison, D; Hotz, P. (2014). Biological monitoring and health effects of low-level exposure to N-methyl-2-pyrrolidone: a cross-sectional study. Int Arch Occup Environ Health. 87(6): 663-674. http://dx.doi.org/10.1007/s00420-013-0906-5.
Hazelton Lab (Hazelton Laboratories, Inc). (1980). Unpublished report, project No. 257-109, 11 Feb. (as cited in OECD, 2007).
HESIS. (2014). N-methylpyrrolidone (nmp): Health haazard advisory: Fact sheet. Richmond, CA. https://www.cdph.ca.gov/programs/hesis/Documents/nmp.pdf.
HSDB. (2017). Hazardous substances data bank: 1-Methyl-2-pyrrolidinone [Database]. Rockville, MD: U.S. National Library of Medicine. Retrieved from https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm
IFA (Institut für Arbeitschutz der Deutschen Gesetzlichen Unfallversicherung). (2010). MEGA evaluations for the preparation of REACH exposure scenarios for N-methyl-2-pyrrolidone (vapour) (pp. 1-15). Institut für Arbeitschutz der Deutschen Gesetzlichen Unfallversicherung :: IFA.
Johnson Matthey Process Technologies. (2017). N-METHYL-2-PYRROLIDONE (NMP) [Website]. http://www.jmprotech.com/licensed-processes-n-methyl-2-pyrrolidone.
Kamienski, CW, McDonald, D. P., Stark, M., and Papcun, J. R. (2004). Lithium and lithium compounds. In Kirk-Othmer Encyclopedia of Chemical Technology. New York, NY: John Wiley & Sons. http://dx.doi.org/10.1002/0471238961.1209200811011309.a01.pub2 ; http://onlinelibrary.wiley.com/doi/10.1002/0471238961.1209200811011309.a01.pub2/abstract.
Keener, SA; Wrbitzky, R; Bader, M. (2007). Human volunteer study on the influence of exposure duration and dilution of dermally applied N-methyl-2-pyrrolidone (NMP) on the urinary elimination of NMP metabolites. Int Arch Occup Environ Health. 80(4): 327-334. http://dx.doi.org/10.1007/s00420-006-0138-z.
Kiefer, M. (1994). Health Hazard Evaluation Report No. HETA-93-0844-2411, Rosebud Company, Atlanta, Georgia (pp. 93-0844). (NIOSH/00220122). Kiefer, M.
Kim, BR; Kalis, EM; Dewulf, T; Andrews, KM. (2000). Henry's law constants for paint solvents and their implications on volatile organic compound emissions from automotive painting. Water Environ Res. 72(1): 65-74.

Lan, CH; Peng, CY; Lin, TS. (2004). Acute aquatic toxicity of N-methyl-2-pyrrolidinone to Daphnia magna. Bull Environ Contam Toxicol. 73(2): 392-397. http://dx.doi.org/10.1007/s00128-004-0441-x.
Meier, S; Schindler, BK; Koslitz, S; Koch, HM; Weiss, T; Käfferlein, HU; Brüning, T. (2013). Biomonitoring of exposure to N-methyl-2-pyrrolidone in workers of the automobile industry. Ann Occup Hyg. 57(6): 766-773. http://dx.doi.org/10.1093/annhyg/mes111.
Mitsubishi Chemical. (2017). NMP/N-methyl-2-pyrrolidone. https://www.m-chemical.co.jp/en/products/departments/mcc/c4/product/1201005_7922.html.
MO DNR. (2001). State of Missouri toxics release inventory: Summary report: 1999 data. Jefferson City, MO: Technical Assistance Office. http://infohouse.p2ric.org/ref/15/14909.pdf.
Muenter, J; Blach, R. (2010). ECOLOGICAL TECHNOLOGY: NMP-FREE LEATHER FINISHING. American Leather Chemists Association Journal. 105(9): 303-308.
NCBI. (2017). PubChem: 1-Methyl-2-pyrrolidinone [Database]. Washington, DC: National Institute of Health, U.S. National Library of Medicine, National Center for Biotechnology Information. Retrieved from https://www.ncbi.nlm.nih.gov/pccompound
NFPA (National Fire Protection Association). (1997). Fire protection guide on hazardous materials (12th ed.). Quincy, MA: National Fire Protection Assoc.
NICNAS (National Industrial Chemicals Notification and Assessment Scheme). (1997). Full public report: Polymer in byk-410. (NA/474). https://www.nicnas.gov.au/__data/assets/word_doc/0015/20058/NA474FR.docx.
NICNAS (National Industrial Chemicals Notification and Assessment Scheme). (1998). Full public report: Copolymer in foraperle 321. https://www.nicnas.gov.au/__data/assets/word_doc/0010/19873/NA588FR.docx.
NICNAS (National Industrial Chemicals Notification and Assessment Scheme). (2001). Full public report: Polymer in primal binder u-51. https://www.nicnas.gov.au/__data/assets/pdf_file/0004/9661/PLC259FR.pdf.
NICNAS (National Industrial Chemicals Notification and Assessment Scheme). (2013). Human health Tier II assessment for 2-pyrrolidinone, 1-methyl, CAS Number 872-50-4. http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=91.
NIOSH (National Institute for Occupational Safety and Health). (1998). Health Hazard Evaluation Report No. HETA 96–0266–2702, Cooper Engineered Products, Bowling Green, Ohio.
NIOSH (National Institute for Occupational Safety and Health). (2014a). Health hazard evaluation report no. HHE-2011-0099-3211, evaluation of employee exposures during sea lamprey pesticide application. (HHE-2011-0099-3211). Cincinnati, OH. https://www.cdc.gov/niosh/hhe/reports/pdfs/2011-0099-3211.pdf.
NIOSH (National Institute for Occupational Safety and Health). (2014b). International chemical safety cards (ICDC): N-methyl-2-pyrrolidone. Atlanta, GA. https://www.cdc.gov/niosh/ipcsneng/neng0513.html.
Nishimura, S; Yasui, H; Miyauchi, H; Kikuchi, Y; Kondo, N; Takebayashi, T; Tanaka, S; Mikoshiba, Y; Omae, K; Nomiyama, T. (2009). A cross-sectional observation of effect of exposure to N-methyl-2-pyrrolidone (NMP) on workers' health. Ind Health. 47(4): 355-362.
NWQMC (National Water Quality Monitoring Council). (2017). Water quality portal. https://www.waterqualitydata.us/.
O'Neil, MJ; Heckelman, PE; Koch, CB. (2006). The Merck index: An encyclopedia of chemicals, drugs, and biologicals (14th ed.). Whitehouse Station, NJ: Merck & Co.
OECD (Organisation for Economic Co-operation and Development). (2007). SIDS Initial Assessment Report on 1-Methyl-2-pyrrolidone. Organization for Economic Cooperation and Development. http://webnet.oecd.org/hpv/ui/handler.axd?id=84daa4ac-feb7-4b5a-9839-206d17914e42.

OECD (Organisation for Economic Co-operation and Development). (2009a). Emission scenario document on adhesive formulation. (JT03263583). Paris, France.
OECD. (2009b). SIDS Dossier. 2- Pyrrolidinone, 1-Methyl. http://webnet.oecd.org/hpv/ui/SponsoredChemicals.aspx.
OECD (Organisation for Economic Co-operation and Development). (2010a). Emission Scenario Document on Formulation of Radiation Curable Coatings, Inks and Adhesives. In Series on Emission Scenario Documents No 21. Paris: OECD Environmental Health and Safety Publications. http://www.oecd-ilibrary.org/docserver/download/9714171e.pdf?expires=1497031714&id=id&accname=guest&checksum=E5B188BBD13C6D7100D39B8643ABA020.
OECD (Organisation for Economic Co-operation and Development). (2010b). Emission Scenario Document on Photoresist Use in Semiconductor Manufacturing. In Series on Emission Scenario Documents No 9. Paris: OECD Environmental Health and Safety Publications. http://dx.doi.org/10.1787/9789264221161-en.
OECD (Organisation for Economic Co-operation and Development). (2010c). Scoping Document for Emission Scenario Document on Manufacturing and Use of Printing Inks. OECD Environmental Health and Safety Publications.
OECD (Organisation for Economic Co-operation and Development). (2011). EMISSION SCENARIO DOCUMENT ON RADIATION CURABLE COATING, INKS AND ADHESIVES. In Series on Emission Scenario Documents No 27. Paris: OECD Environmental Health and Safety Publications. http://www.oecd-ilibrary.org/docserver/download/9714111e.pdf?expires=1497031939&id=id&accname=guest&checksum=C794B2987D98D1D145225EAF9B482280.
OECD. (2015). Emission scenario document on use of adhesives. (Number 34). Paris, France. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2015)4&doclanguage=en.
OECD (Organisation for Economic Co-operation and Development). (2017). Emission Scenario Document (ESD) on the use of textile dyes. http://www.oecd.org/chemicalsafety/risk-assessment/emissionscenariodocuments.htm.
OEHHA (California Office of Environmental Health Hazard Assessment). (2003). Proposition 65 maximum allowable dose level (MADL) for reproductive toxicity for N-Methypyrrolidone for Dermal and Inhalation Exposures.
OEHHA. (2007). Occupational health hazard risk assessment project for California: Identification of chemicals of concern, possible risk assessment methods, and examples of health protective occupational air concentrations. Sacramento, CA. http://www.cdph.ca.gov/programs/hesis/Documents/riskreport.pdf.
OSHA (Occupational Safety & Health Administration). (2017a). Chemical Exposure Health Data (CEHD) provided by OSHA to EPA. U.S. Occupational Safety and Health Administration.
OSHA (Occupational Safety & Health Administration). (2017b). Sampling and analytical methods: N-methyl-2-pyrrolidinone. Washington, DC: U.S. Department of Labor, Occupational Safety and Health Administration. https://www.osha.gov/dts/sltc/methods/partial/pv2043/2043.html.
Riddick, JA; Bunger, WB; Sakano, TK. (1986). Techniques of organic chemistry: Organic solvents: Physical properties and methods of purification (4th ed.). New York, NY: Wiley-Blackwell.
RIVM (National Institute for Public Health and the Environment (Netherlands)). (2013). Annex XV Restriction Report: Proposal for a Restriction. In RIVM, Bureau REACH. (Version 2). The Netherlands: National Institute for Public Health and the Environment (RIVM). https://echa.europa.eu/documents/10162/13641/nmp_annex_xv_report_en.pdf.
Sasaki, H; Kojima, M; Mori, Y; Nakamura, J; Shibasaki, J. (1988). Enhancing effect of pyrrolidone derivatives on transdermal drug delivery. 1. Int J Pharm. 44(1-3): 15-24.

Solomon, GM; Morse, EP; Garbo, MJ; Milton, DK. (1996). Stillbirth after occupational exposure to N-methyl-2-pyrrolidone: A case report and review of the literature [Review]. J Occup Environ Med. 38(7): 705-713. http://dx.doi.org/10.1097/00043764-199607000-00014.

Stevens, GW; Lo, TC; Baird, MHI. (2007). Extraction, Liquid-Liquid. In Kirk-Othmer Encyclopedia of Chemical Technology. New York, NY: John Wiley & Sons. http://dx.doi.org/10.1002/0471238961.120917211215.a01.pub2.

Technikon LLC. (2001). Core box cleaner study: Evaporative emission study of specialty systems' solvent FC-47-G1. (RC200098DC). McClellan, CA: Casting Emission Reduction Program. http://www.afsinc.org/files/dc-12gsa2%20core%20box%20cleaner%20studysec_1383852934984_29.pdf.

TURI (Toxics Use Reduction Institute). (1996). N-methyl pyrrolidone: Chemical profile. Lowell, MA: The Toxics Use Reduction Institute. http://infohouse.p2ric.org/ref/34/33540.pdf.

U.S. EPA (U.S. Environmental Protection Agency). (1998a). Cleaner technologies substitutes assessment for professional fabricare processes: Appendix F: Chemical volume estimates: Screen printing CTSA. Washington, DC: Office of Pollution Prevention and Toxics. http://infohouse.p2ric.org/ref/01/00937/app-f.pdf.

U.S. EPA (U.S. Environmental Protection Agency). (1998b). Environmental profile for N-methylpyrrolidone. (EPA/600/R-98/067). Washington, DC. https://cfpub.epa.gov/si/si_public_record_Report.cfm?dirEntryID=99474.

U.S. EPA (U.S. Environmental Protection Agency). (1998c). Guidelines for ecological risk assessment [EPA Report]. (EPA/630/R-95/002F). Washington, DC: U.S. Environmental Protection Agency, Risk Assessment Forum. http://www.epa.gov/raf/publications/guidelines-ecological-risk-assessment.htm.

U.S. EPA. (1999). Category for persistent, bioaccumulative, and toxic new chemical substances. Fed Reg. 64(213): 60194-60204.

U.S. EPA (U.S. Environmental Protection Agency). (2000). Science policy council handbook: Risk characterization (pp. 1-189). (EPA/100/B-00/002). Washington, D.C.: U.S. Environmental Protection Agency, Science Policy Council. https://www.epa.gov/risk/risk-characterization-handbook.

U.S. EPA (U.S. Environmental Protection Agency). (2002). Guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity, of information disseminated by the Environmental Protection Agency. (EPA/260/R-02/008). Washington, DC: U.S. Environmental Protection Agency, Office of Environmental Information. http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

U.S. EPA (U.S. Environmental Protection Agency). (2006a). EPA Action Memorandum: Inert Reassessment: N-methylpyrrolidone (CAS Reg. No. 872-50-4). https://www.epa.gov/sites/production/files/2015-04/documents/methyl.pdf.

U.S. EPA (U.S. Environmental Protection Agency). (2006b). A framework for assessing health risk of environmental exposures to children (pp. 1-145). (EPA/600/R-05/093F). Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158363.

U.S. EPA (U.S. Environmental Protection Agency). (2007). Technical Support Document for Proposed Rule: National Emission Standards for Hazardous Air Pollutants: Paint Stripping Operations at Area Sources. Research Triangle Park, NC. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-20050526-0019.

U.S. EPA (U.S. Environmental Protection Agency). (2011). Exposure factors handbook: 2011 edition (final) [EPA Report]. (EPA/600/R-090/052F). Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=236252.

U.S. EPA (U.S. Environmental Protection Agency). (2012a). Benchmark dose technical guidance. (EPA/100/R-12/001). Washington, DC: U.S. Environmental Protection Agency, Risk Assessment Forum. https://www.epa.gov/risk/benchmark-dose-technical-guidance.
U.S. EPA (U.S. Environmental Protection Agency). (2012b). Estimation Programs Interface Suite™ for Microsoft® Windows, v4.10. Washington, DC: US Environmental Protection Agency. http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm.
U.S. EPA. (2012c). Storage and retrieval (STORET) data warehouse and water quality exchange (WQX) [database] [Database]. Washington, DC. Retrieved from http://www.epa.gov/storet/
U.S. EPA (U.S. Environmental Protection Agency). (2012d). Sustainable futures P2 framework manual [EPA Report]. (EPA-748-B12-001). Washington DC. http://www.epa.gov/sustainable-futures/sustainable-futures-p2-framework-manual.
U.S. EPA (U.S. Environmental Protection Agency). (2013). Interpretive assistance document for assessment of discrete organic chemicals. Sustainable futures summary assessment [EPA Report]. Washington, DC. http://www.epa.gov/sites/production/files/2015-05/documents/05-iad_discretes_june2013.pdf.
U.S. EPA (U.S. Environmental Protection Agency). (2014). Framework for Human Health Risk Assessment to Inform Decision Making. (EPA/100/R-14/001). Washington, DC: Environmental Protection Agency, Office of the Science Advisor. https://www.epa.gov/sites/production/files/2014-12/documents/hhra-framework-final-2014.pdf.
U.S. EPA (U.S. Environmental Protection Agency). (2015). TSCA work plan chemical risk assessment. N-Methylpyrrolidone: Paint stripper use (CASRN: 872-50-4). In Office of Chemical Safety and Pollution Prevention. (740-R1-5002). Washington, DC. https://www.epa.gov/sites/production/files/2015-11/documents/nmp_ra_3_23_15_final.pdf.
U.S. EPA (U.S. Environmental Protection Agency). (2016a). Instructions for reporting 2016 TSCA chemical data reporting. Washington, DC: Office of Pollution Prevention and Toxics. https://www.epa.gov/chemical-data-reporting/instructions-reporting-2016-tsca-chemical-data-reporting.
U.S. EPA. (2016b). Public database 2016 chemical data reporting (May 2017 release). Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics. Retrieved from https://www.epa.gov/chemical-data-reporting
U.S. EPA. (2016c). Toxic release inventory: N-methyl-2-pyrrolidone [Database].
U.S. EPA (U.S. Environmental Protection Agency). (2017a). Scope of the risk evaluation for N-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-). CASRN: 872-50-4 [EPA Report]. (EPA-740-R1-7005). https://www.epa.gov/sites/production/files/2017-06/documents/nmp_scope_6-22-17_0.pdf.
U.S. EPA. (2017b). Toxics Release Inventory (TRI). Retrieved from https://www.epa.gov/toxics-release-inventory-tri-program/tri-data-and-tools
U.S. EPA (U.S. Environmental Protection Agency). (2018). Application of systematic review in TSCA risk evaluations: DRAFT Version 1.0. (740P18001). Washington, D.C.: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention.
White, DL; Bardole, JA. (2004). Paint and finish removers.
WHO (World Health Organization). (2001). Concise International Chemical Assessment Document 35: N-Methyl-2-Pyrrolidone. Geneva, Switzerland. http://www.inchem.org/documents/cicads/cicads/cicad35.htm.
Xiaofei, E; Wada, Y; Nozaki, J; Miyauchi, H; Tanaka, S; Seki, Y; Koizumi, A. (2000). A linear pharmacokinetic model predicts usefulness of N-methyl-2-pyrrolidone (NMP) in plasma or urine as a biomarker for biological monitoring for NMP exposure. J Occup Health. 42(6): 321-327.

APPENDICES

Appendix A REGULATORY HISTORY

A.1 Federal Laws and Regulations

Table_Apx A-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
Toxic Substances Control Act (TSCA) – Section 6(a)	Provides EPA with the authority to prohibit or limit the manufacture (including import), processing, distribution in commerce, use or disposal of a chemical if EPA evaluates the risk and concludes that the chemical presents an unreasonable risk to human health or the environment.	Proposed rule (82 FR 7464) regulating NMP uses in paint and coating removal
Toxic Substances Control Act (TSCA) – Section 6(b)	Directs EPA to promulgate regulations to establish processes for prioritizing chemicals and conducting risk evaluations on priority chemicals. In the meantime, EPA is directed to identify and begin risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.	NMP is on the initial list of chemicals to be evaluated for unreasonable risk under TSCA (81 FR 91927, December 19, 2016)
Toxic Substances Control Act (TSCA) – Section8(a)	The TSCA section 8(a) Chemical Data Reporting (CDR) Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the US.	NMP manufacturing, importing, processing and use information is reported under the Chemical Data Reporting (CDR) rule (76 FR 50816, August 16, 2011).
Toxic Substances Control Act (TSCA) – Section8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured, processed, or imported in the United States.	NMP was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process (60 FR 16309, March 29, 1995).
Toxic Substances Control Act (TSCA) – Section 8(e)	Manufacturers (including importers), processors and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	Seven notifications of substantial risk (Section 8(e)) received (2007 – 2010) (US EPA, ChemView. Accessed April 13, 2017).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Toxic Substances Control Act (TSCA) – Section 4	Provides EPA with authority to issue rules and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	Six submissions from a test rule (Section 4) received in the mid-1990s. (US EPA, ChemView. Accessed April 13, 2017).
Emergency Planning and Community Right-To-Know Act (EPCRA) – Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full time equivalent employees and that manufacture, process, or otherwise use a TRI-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (e.g., quantities recycled, treated, combusted) and pollution prevention activities (under section 6607 of the Pollution Prevention Act). This data includes on-site and off-site data as well as multimedia data (i.e., air, land and water).	NMP is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1995.
Federal Food, Drug and Cosmetic Act (FFDCA) – Section 408	FFDCA governs the allowable residues of pesticides in food. Section 408 of the FFDCA provides EPA with the authority to set tolerances (rules that establish maximum allowable residue limits), or exemptions from the requirement of a tolerance, for all residues of a pesticide (including both active and inert ingredients) that are in or on food. Prior to issuing a tolerance or exemption from tolerance, EPA must determine that the tolerance or exemption is "safe." Sections 408(b) and (c) of the FFDCA define "safe" to mean the Agency has a reasonable certainty that no harm will result from aggregate exposures to the pesticide residue, including all dietary exposure and all other exposure (e.g., non-occupational exposures) for which there is reliable information. Pesticide tolerances or exemptions from tolerance that do not meet the FFDCA safety standard are subject to revocation. In the absence of a tolerance or an exemption from tolerance, a food containing a pesticide residue is considered adulterated and may not be distributed in interstate commerce.	NMP is currently approved for use as a solvent and co-solvent inert ingredient in pesticide formulations for both food and non-food uses and is exempt from the requirements of a tolerance limit (40 CFR Part 180.920).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Clean Air Act (CAA) – Section 111 (b)	Requires EPA to establish new source performance standards (NSPS) for any category of new or modified stationary sources that EPA determines causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare. The standards are based on the degree of emission limitation achievable through the application of the best system of emission reduction which (considering the cost of achieving reductions and non-air quality health and environmental impacts and energy requirements) EPA determines has been adequately demonstrated.	NMP is subject to Clean Air Act Section 111 Standards of Performance for New Stationary Sources of Air Pollutants for VOC emissions from synthetic organic chemical manufacturing industry distillation operations (40 CFR Part 60, subpart NNN) and reactor processes (40 CFR Part 60, Subpart RRR).
Clean Air Act (CAA) – Section 183(e)	Section 183(e) requires EPA to list the categories of consumer and commercial products that account for at least 80 percent of all VOC emissions in areas that violate the National Ambient Air Quality Standards for ozone and to issue standards for these categories that require "best available controls." In lieu of regulations, EPA may issue control techniques guidelines if the guidelines are determined to be substantially as effective as regulations.	NMP is listed under the National Volatile Organic Compound Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E).
Clean Air Act (CAA) – Section 612	Under Section 612 of the Clean Air Act (CAA), EPA's Significant New Alternatives Policy (SNAP) program reviews substitutes for ozone depleting substances within a comparative risk framework. EPA publishes lists of acceptable and unacceptable alternatives. A determination that an alternative is unacceptable, or acceptable only with conditions, is made through rulemaking.	Under EPA's SNAP program, EPA listed NMP as an acceptable substitute for "straight organic solvent cleaning (with terpenes, C620 petroleum hydrocarbons, oxygenated organic solvents such as ketones, esters, alcohols, etc.)" for metals, electronics and precision cleaning and "Oxygenated organic solvents (esters, ethers, alcohols, ketones)" for aerosol solvents (59 FR, March 18, 1994).
Safe Drinking Water Act (SDWA) – Section 1412 (b)	Every 5 years, EPA must publish a list of contaminants (1) that are currently unregulated, (2) that are known or anticipated to occur in public water systems,	NMP was identified on both the Third (2009) and Fourth (2016) Contaminant Candidate Lists (74

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	and (3) which might require regulations under SDWA. EPA must also determine whether to regulate at least five contaminants from the list every 5 years.	FR 51850, October 8, 2009) (81 FR 81099 November 17, 2016).
Other Federal Regulations		
Occupational Safety and Health Act (OSHA)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress, or unsanitary conditions. Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative control measures and respiratory protection.	OSHA has not established a PEL for NMP, though OSHA identifies potential symptoms and health effects associated with NMP including eye irritation, severe skin irritation with chronic exposure and reproductive hazards including possible fetal toxicity.
Federal Food, Drug and Cosmetic Act (FFDCA)	Provides the U.S Food and Drug Administration (FDA) with authority to oversee the safety of food, drugs and cosmetics.	Food and Drug Administration identifies NMP as an "Indirect Additive Used in Food Contact Substances" specifically as: 1) an adjuvant substance in the preparation of slimicides (21 CFR 176.300), 2) an adjuvant substance in the production of polysulfone resin authorized for use as articles intended for use in contact with food (21 CFR 177.1655) and 3) a residual solvent in polyetherone sulfone resins authorized as articles for repeated use in contact with food (21 CFR 177.2440). FDA also identifies NMP as a Class 2 solvent, namely a solvent that "should be limited in pharmaceutical products because of their inherent toxicity." FDA established a Permissible Daily Exposure (PDE) for NMP of 5.3 mg/day with a concentration limit of 530 ppm. FDA's Center for Veterinary Medicine developed a method in

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		2011 for detection of the residues of NMP in edible tissues of cattle (21 CFR 500.1410)

A.2 State Laws and Regulations

Table_Apx A-2. State Laws and Regulations

State Actions	Description of Action
State Air Regulations	New Hampshire (Env-A 1400: Regulated Toxic Air Pollutants) lists NMP as a regulated toxic air pollutant. Vermont (Vermont Air Pollution Control Regulations, 5261) lists NMP as a hazardous air contaminant.
Chemicals of Concern to Children	Several states have adopted reporting laws for chemicals in children's products that include NMP including Oregon (OAR 333-016-2000), Vermont (18 V.S.A. sections 1771 to 1779) and Washington state (WAC 173-334-130). Minnesota has listed NMP as a chemical of concern to children (Minnesota Statutes 116.9401 to 116.9407).
State Permissible Exposure Limits	California PEL is 1 ppm as an 8hr-time-weighted average (TWA), along with a skin notation (Cal Code Regs, title 8, section 5155).
State Right-to-Know Acts	Massachusetts (454 CMR 21.00), New Jersey (42 N.J.R. 1709(a)) and Pennsylvania (Chapter 323. Hazardous Substance List).
Other	In California, NMP is listed on Proposition 65 (Cal. Code Regs. title 27, section 27001) due to reproductive toxicity. California OEHHA lists a Maximum Allowable Dose Level (MADL) for inhalation exposure = 3,200 µg/day MADL for dermal exposure = 17,000 µg/day. The California Department of Toxic Substances Control (DTSC) Safer Consumer Products Program lists NMP as a Candidate Chemical for development toxicity and reproductive toxicity. In addition, DTSC is moving to address paint strippers containing NMP and specifically cautioned against replacing Methylene Chloride with NMP. California is considering a separate rule on NMP. California Department of Public Health's Hazard Evaluation System and Information Service (HESIS) issued a Health Hazard Advisory on NMP in 2006 and updated the Advisory in June 2014. The Advisory is aimed at workers and employers at sites where NMP is used.

A.3 International Laws and Regulations

Table_Apx A-3. Regulatory Actions by Other Governments and Tribes

Country/Organization	Requirements and Restrictions
European Union	In 2011, NMP was listed on the Candidate list as a Substance of Very High Concern (SVHC) under regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals). In March 2017, NMP was included in the public consultation of chemicals recommended for inclusion in Annex XIV of the European Chemicals Agency (ECHA) under Annex (Authorisation list) of regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals). In 2013, the Netherlands submitted a proposal under REACH to restrict manufacturing and all industrial and professional uses of NMP where workers' exposure exceeds a level specified in the restriction (European Chemicals Agency (ECHA) database. Accessed April 18, 2017). On April 18, 2018, the European Union added NMP to REACH Annex XVII, the restricted substances list. The action specifies three conditions of restriction. The conditions are: 1) NMP shall not be placed on the market as a substance on its own or in mixtures in concentrations greater than 0.3% after May 9, 2020, unless manufacturers, importers and downstream users have included chemical safety reports and safety data sheets with Derived No-Effect Levels (DNELs) relating to workers' exposures of 14.4 mg/m3 for exposure by inhalation and 4.8 mg/kg/day for dermal exposure; 2) NMP shall not be manufactured, or used, as a substance on its own or in mixtures in a concentration equal to or greater than 0.3% after May 9, 2020 unless manufacturers and downstream users take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the DNELs specified above: and 3) the restrictions above shall apply from May 9, 2024 to placing on the market for use, or use, as a solvent or reactant in the process of coating wires.
Australia	NMP was assessed under Human Health Tier III of the Inventory Multi-tiered Assessment and Prioritisation (IMAP) (National Industrial Chemicals Notification and Assessment Scheme, NICNAS, 2017, Human Health Tier III assessment for 2-Pyrrolidinone, 1methyl-. Accessed April, 18 2017).
Japan	NMP is regulated in Japan under the following legislation: • Act on the Evaluation of Chemical Substances and Regulation of their Manufacture, etc. (Chemical Substances Control Law; CSCL) • Industrial Safety and Health Act (National Institute of Technology and Evaluation (NITE) Chemical Risk Information Platform (CHIRP). Accessed April 18, 2017).

Country/Organization	Requirements and Restrictions
European Union and Australia, Austria, Belgium, Canada (Ontario), Denmark, Finland, France, Germany, Ireland, Italy, Latvia, New Zealand, Poland, Spain, Sweden, Switzerland, The Netherlands, Turkey and the United Kingdom.	Occupational exposure limits for NMP (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 18, 2017).

Appendix B PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found during preliminary data gathering for NMP.

B.1 Process Information

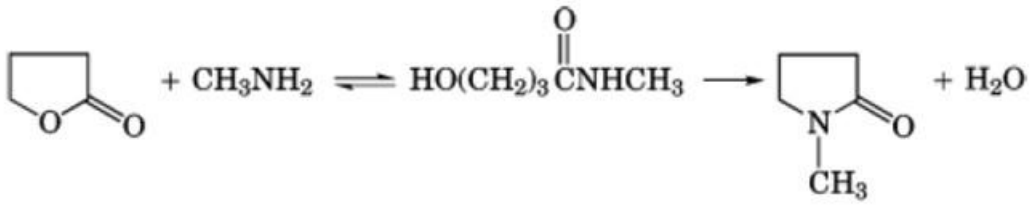
Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities for consideration. Note that the processing information below is representative of NMP, but not inclusive of all uses. EPA will consider this information and data in combination with other data and methods for use in the risk evaluation.

B.1.1 Manufacture (Including Import)

According to 2016 public CDR data, NMP is both domestically manufactured in and imported into the United States (U.S. EPA, 2016b).

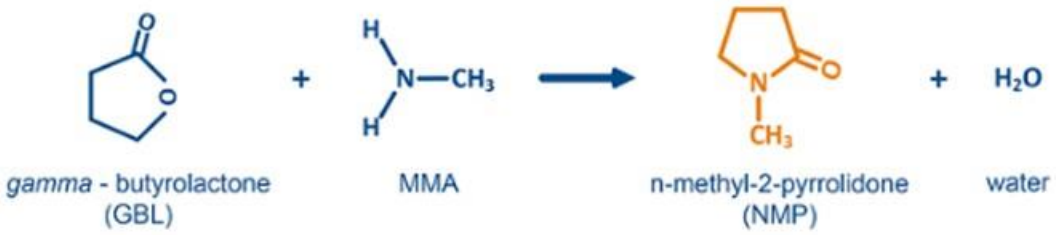
B.1.1.1 Domestic Manufacturing

NMP can be manufactured using different methods. One method involves reaction of butyrolactone with an excess of pure or aqueous methylamine in a high pressure tube (Harreus et al., 2011). This reaction is shown in Figure_Apx B-1 and is taken from (Anderson and Liu, 2000). This exothermic reaction takes place under adiabatic conditions, and produces a reaction product containing NMP that is subsequently distilled to purify the NMP produced. This method of manufacturing results in a 97% yield of NMP (Harreus et al., 2011).



Figure_Apx B-1. NMP Manufacturing Under Adiabatic Conditions

Another process for manufacturing NMP involves reacting gamma-butyrolactone (GBL) and monomethylamine (MMA), as shown in Figure_Apx B-2 (Johnson Matthey Process Technologies, 2017). This reaction is non-catalyzed and takes place in two stages. The first stage produces a long-chain amide that is cyclized, then dehydrated to form NMP during the second stage of the reaction. The reaction product which contains NMP is then distilled to purify the NMP.



Figure_Apx B-2. NMP Manufacturing Using Gamma-Butyrolactone (GBL) and Monomethylamine (MMA)

NMP is also manufactured from maleic anhydride in an integrated production process at a Mitsubishi plant in Japan (Mitsubishi Chemical, 2017).

B.1.1.2 Import

Typical import activities for NMP include storage in warehouses prior to distribution for further processing and use and quality control sampling.

Transfers of NMP are generally done with steel piping, as rubber hose is not suitable for handling. NMP may be transported in tank cars, tank trailers or drums. Shipping containers normally consist of unlined steel (Anderson and Liu, 2000).

B.1.2 Processing

B.1.2.1 Reactant/Intermediate

The exact process operations involved during the use of NMP as a chemical intermediate are dependent on the final product that is being synthesized. For NMP use as a chemical intermediate, operations would typically involve unloading NMP from transport containers and feeding it into reaction vessel(s), where the NMP would either react fully or to a lesser extent. Following completion of the reaction, the produced substance may or may not be purified further, thus removing unreacted NMP (if present). The reacted NMP is assumed to be destroyed and therefore is not expected to be released to the environment or to present a potential for worker exposure.

B.1.2.2 Incorporation into Formulation, Mixture, or Reaction Product

NMP is incorporated into formulations for a wide range of products, including cleaning products, paints, coatings, adhesives, sealants, inks and toners (ECHA, 2011). Formulation processes for these products typically involve similar operations. First, the components of the product formulation are unloaded from transport containers, either directly into the mixing equipment or into an intermediate storage vessel. Transfer from transport containers may be manual or automated, through the use of a pumping system. An automated dispenser may be used to feed components into the mixing vessel to ensure that precise amounts are added at the proper time during the mixing process. Once in the mixing vessel, the components are then mixed in either a batch or continuous system. Evaporative losses of NMP and other volatile components will depend on whether a closed or open system is used during the mixing process (OECD, 2010a).

Depending on the specific product, the formulation may be further processed through filtering. Once the formulation is completed, it is sampled for quality purposes. The final formulation is then filled into containers, either through manual dispensing from transfer lines or through utilization of an automatic system. Automatic filling systems are generally used for the filling of smaller containers that are

intended for consumer and commercial applications, whereas manual filling is done for larger containers (e.g., tank trucks, totes, drums) which are typically used in an industrial setting (OECD, 2010a).

B.1.2.3 Incorporation into Article

EPA defines articles as manufactured items that are formed to a specific shape or design during manufacture and for which the end use is dependent in whole or in part upon their shape or design. The exact process operations involved in the incorporation of NMP are dependent on the article. Incorporation into an article typically refers to a process in which a chemical becomes an integral component of an article (as defined at 40 CFR 704.3) for distribution in commerce. The exact process operations involved in the incorporation of NMP-containing formulations or reaction products are dependent on the article. EPA identified the following processing activities that incorporate NMP and NMP formulations or reaction products into articles.

B.1.2.4 Repackaging

Typical repackaging operations involve transferring of NMP into appropriately sized containers to meet customer demands/needs.

B.1.2.5 Recycling

NMP is used as an extractive solvent for effective removal of various compounds by petrochemical and other industries (ECHA, 2011). In this capacity, NMP absorbs the compound being extracted and can be regenerated and recycled for reuse; this is described in further detail in the Petrochemical Processing Aid section.

B.1.3 Uses

In this document, EPA has grouped uses based on CDR categories and identified examples within these categories as subcategories of use. Note that some subcategories may be grouped under multiple CDR subcategories. These differences will be further investigated and refined during risk evaluation.

B.1.3.1 Paints and Coatings

The physical-chemical properties of NMP make it miscible in water and many hydrocarbon solvents, allowing NMP to be used in a diverse range of paint and coating applications (ECHA, 2011). The components of the paint or coating are formulated as discussed in the previous section. Note that many paint and coating formulations are filtered to remove any undesired solids (such as gel, pigment or filler agglomerates) (OECD, 2010a) prior to packaging into transport containers.

Containers of formulated paints and coating products are then sent to the customer for application, where they may be diluted and mixed prior to application (OECD, 2011). Application techniques include brushing, rolling, spraying, printing, dipping and curtain coating, and may be manual or automated. Once applied to the substrate, the paint or coating is allowed to dry or “cure” during this time, the NMP in the coating evaporates completely (ECHA, 2011). The drying/curing process may be promoted through the use of heat or radiation (radiation can include ultraviolet and electron beam radiation), but this more common for waterborne coatings (OECD, 2010a). Due to its evaporation potential, NMP is not assumed to be present in articles after the drying/curing process is complete (ECHA, 2011).

NMP is used for paint removal in a variety of industries, such as the automotive, aircraft, construction and refinishing industries. Application methods include manual or automated, with techniques such as spraying, brushing, pouring, wiping and rolling. Additional details on this use of NMP can be found in the previous risk assessment which evaluated the use of NMP in paint and coating removal (U.S. EPA, 2015).

B.1.3.2 Solvents for Cleaning and Degreasing

NMP is used in a variety of cleaning products, because of its high solvating power for plastics, resins, oil and grease (ECHA, 2011). NMP is used in industrial cleaners and degreasers, graffiti-removing products and consumer cleaning products. NMP is also used in the electronics industry as a solvent carrier in photoresist formulations, and for removal of excess photoresist from silicon wafers (ECHA, 2011).

Once formulated, cleaning solutions containing NMP can be applied to substrates using a variety of application methods, including roller application, brushing, dipping, pouring, spraying and wiping. NMP application may be automated or manual, depending on the cleaning product. Consumer cleaning solutions are likely to be applied manually, whereas industrial cleaning processes are often automated. The applied cleaning solution is then removed from the substrate, along with the contaminants, and discarded as waste.

Degreasing operations are used to remove dirt, grease and surface contaminants from the substrate. NMP is reportedly used as a solvent in degreasing tanks in the aerospace industry (ECHA, 2011). Industrial degreasing operations can involve batch or continuous processes; actual operation can include vapor-phase and/or liquid-phase degreasing (e.g., cold cleaning) (U.S. EPA, 2016b).

Photoresist formulations containing solvents, such as NMP, are applied using a dispensing apparatus that applies small amounts of photoresist formulations to wafers, which are then spun at a high speed to uniformly coat their surface. The excess photoresist that is spun off of the wafer is then disposed of as waste. The coated wafers are subsequently baked to evaporate the carrier solvent, exposed to form an image and then baked again to ensure that trace amounts of solvent are evaporated (OECD, 2010b). Wafers are then developed to dissolve unwanted portions of the photoresist and etched to remove unwanted areas of silicon substrate or deposited film before the residual photoresist is removed. Wet removal processes involve submersion of wafers in a bath solution containing chemicals such as solvents, acids or bases, to dissolve the photoresist. The waste bath containing the dissolved photoresist is collected, and potentially treated, prior to disposal (OECD, 2010b).

B.1.3.3 Ink, Toner and Colorant Products

Printing inks are comprised of colorants (e.g., pigments, dyes and toners) dispersed in a formulation to form a paste, liquid or solid which can be applied to a substrate surface and dried (OECD, 2010c). In addition to colorants, ink formulations contain several types of substances including solvents such as NMP, binders, thinners, dispersing agents and drying agents. During product formulation, colorants are generally added after all of the other components have been combined and mixed. Dispersion usually involves a milling process, to break up and evenly distribute the colorant throughout the formulation.

Transport containers for inks and toners can vary widely depending on the intended end use of the product formulation. Consumer products are packaged into smaller containers, such as cartridges for printing or writing inks, whereas product formulations intended for industrial printing operations are generally packaged into larger (e.g., 1-5-gallon) containers (OECD, 2010c).

Industrial printing processes can be categorized as lithographic, flexographic, gravure, letterpress, screen printing or digital printing. Commercial printing may involve lithographic, flexographic, gravure and letterpress printing - all of which involve the transfer of images from printing plates to a substrate. Screen printing requires a mesh screen to transfer the ink to a substrate, whereas digital printing allows for the transfer of a digital image directly onto a substrate. Inkjet printing is the most common form of digital printing. It involves the application of small drops of ink onto a substrate, with direct contact

between the ink nozzle and the substrate. Consumer printing is generally limited to digital inkjet printing; however, consumers also use inks that are pre-loaded into a pen prior to distribution in commerce (ECHA, 2011).

B.1.3.4 Processing Aids Specific to Petroleum Production

NMP is used as a petrochemical processing aid in a variety of applications including extraction of aromatic hydrocarbons from lube oils; separation and recovery of aromatic hydrocarbons from mixed hydrocarbon feedstocks; recovery of acetylenes, olefins and diolefins; removal of sulfur compounds from natural gas and refinery gases; and dehydration of natural gas (Anderson and Liu, 2000).

Extractive distillation involves distillation in the presence of a solvent (or mixture of solvents) which acts as a separating agent, displaying both a selectivity for, and the capacity to solubilize components in a mixture to be separated (Doherty and Knapp, 2004). Solvents interact differently with the components of the mixture to be separated, thereby altering their relative volatility and allowing them to be separated. Solvent are added near the top of the extractive distillation column, while the mixture to be separated is added at a second feed point further down the column. The component with the higher volatility in the presence of a solvent is distilled overhead as the distillate and components with lower volatility are removed with the solvent in the column bottoms. The solvent is then separated from other components of the mixture, generally through distillation in a second column, and then recycled back to the extractive distillation column (Doherty and Knapp, 2004).

NMP is used both for the extraction of unwanted aromatics from lube oils and the recovery of hydrocarbons from feedstocks, via extractive distillation (ECHA, 2011). NMP is favorable for the extractive distillation of hydrocarbons because hydrocarbons are highly soluble in NMP, and the use of NMP for extraction does not lead to the formation of azeotropes. NMP also has high resistance to heat and chemicals (Stevens et al., 2007).

Other uses of NMP in petrochemical processing involve first using NMP to absorb specific compounds, then separating the NMP from the absorbed compounds, similar to the extractive distillation process (Anderson and Liu, 2000). Examples of absorptive processes include NMP use in the recovery of acetylenes, olefins and diolefins; removal of sulfur compounds from natural and refinery gases; and the dehydration of natural gas.

Absorption using a solvent, such as NMP, generally involves two towers, an absorption tower and a removal tower. The mixture to be separated and the solvent are first introduced into the absorption tower. Here the solvent absorbs the miscible compound and this heavier stream leaves in the bottoms of the column. The solvent mixture is then sent to another column where the absorbed compound is recovered from the solvent. The solvent may undergo further processes, such as scrubbing, to be fully regenerated before being recycled back into the absorption column (Gannon and Schaffer, 2003). (Information specific to the use of NMP for hydraulic fracturing operations was not identified.)

B.1.3.5 Adhesives and Sealants

NMP is used as a component in the formulation of solvent-based adhesives and sealants (OECD, 2009a). Once the adhesive or sealant is received by the user, it may be diluted or mixed prior to application (OECD, 2015). The adhesive formulation is then loaded into the application reservoir or apparatus and applied to the substrate via spray, roll, curtain, syringe or bead application which may be manual or automated. After application, the adhesive or sealant is allowed to dry, usually at ambient temperature. During this time the solvent completely evaporates and a bond is formed between the

substrates. In some instances, heat is applied to the substrate to promote the drying or curing of the adhesive or sealant (OECD, 2015).

B.1.3.6 Other Uses

A number of other uses have been identified for NMP, including laboratory use for various research and cleaning purposes. These activities typically occur within a fume hood, on a bench with local exhaust ventilation, or under conditions that include general ventilation (ECHA, 2011).

Lithium Ion Battery Manufacturing

NMP use as a solvent for electrode preparation and in electrolyte formulations used for lithium ion battery manufacturing is growing (Daniel, 2008). Electrolyte formulations usually include a lithium salt dissolved in a solvent-based solution (Kamienski, 2004). The electrolyte is formulated separately, then filled into the assembled cell, which consists of the electrode structures. Once the electrolyte solution is added, the battery is sealed.

Pharmaceuticals

NMP is increasingly being used as a solvent and extraction medium for the manufacture and formulation of pharmaceuticals (ECHA, 2011).

Reaction Medium

in industry, NMP is often used as a reaction medium for polymerization reactions, because many polymers are soluble in NMP (Anderson and Liu, 2000). Specific polymers that are soluble in NMP include polyvinyl acetate, polyvinyl fluoride, polystyrene, nylon, polyimides, polyesters, acrylics, polycarbonates and synthetic elastomers. Depending on the intended product, once the polymer is synthesized in the NMP-containing reaction medium, it may be isolated and precipitated. However, some polymer-based resin and coating formulations, such as polyurethane dispersions, will include NMP in the final formulation (BPI, 2017). Additional uses of NMP as a reaction medium have not been identified.

Textiles and Clothing

NMP has been found in textiles; however, EPA has not identified information specific to the use of NMP in the textile industry.

B.1.4 Disposal

NMP is not designated as a hazardous substance under federal regulations thus, there are no federal regulations determining how NMP and NMP-containing products may be disposed. However, three states, Massachusetts, New Jersey and Pennsylvania have designated NMP as a hazardous substance, thereby regulating NMP disposal. EPA has not identified other specific NMP disposal information.

B.2 Occupational Exposure Data

EPA presents herein some examples of occupational exposure-related information for NMP obtained from preliminary data gathering. EPA expects to consider this information in combination with other readily available data and methods for use in risk evaluation.

Table_Apx B-1 and Table_Apx B-2 show mappings of release and worker exposure scenarios to industry sectors with available OSHA monitoring data obtained from OSHA inspections between 2002 and 2016 for personal monitoring data and area monitoring data, respectively. EPA attempted to group industry sectors, designated by North American Industry Classification System (NAICS) code,

according to possible release/exposure scenarios, but there is a great degree of uncertainty where and how NMP may be used in these industries. The industry sectors in Table_Apx B-1 and Table_Apx B-2 were extracted from the OSHA CEHD (OSHA, 2017a).

EPA also found some NIOSH HHE data since 2000 that are summarized and included in Table_Apx B-3.

Table_Apx B-1. Mapping of Scenarios to Industry Sectors with NMP Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2012 and 2016

Possible Release/Exposure Scenario	NAICS	NAICS Description
Paint stripping; Adhesive removal by contractors; Roll/curtain, spray, or manual application of lacquers, stains, varnishes, and primers	811420	Reupholstery and Furniture Repair
Aerosol degreasing; Wipe cleaning; Spray, manual (brushing), or dip application of metal finishing products;	333249	Other Industrial Machinery Manufacturing
Unknown – this establishment is an OSHA facility	923110	Administration of Education Programs

[a] Samples are not 8-hr TWA. Results include non-detects (below limit of quantification) and exclude blank samples.

Table_Apx B-2. Mapping of Scenarios to Industry Sectors with NMP Area Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2012 and 2016

Possible Release/Exposure Scenario	NAICS	NAICS Description
Paint stripping; Adhesive removal by contractors; Roll/curtain, spray, or manual application of lacquers, stains, varnishes, and primers	811420	Re-upholstery and Furniture Repair

[a] Samples are not 8-hr TWA. Results include non-detects (below limit of quantification) and exclude blank samples.

Table_Apx B-3. Summary of NIOSH HHE NMP Data

Exposure/Release Scenario	Facility Description	Number of Exposure Samples	Minimum of Exposure Values (ppm)	Maximum of Exposure Values (ppm)	Comments	Source
Paint and coating removal	Floor refinishing	7 (PBZ) 13 (Area)	1.4 (PBZ) 2.2 (Area)	5.2 (PBZ) 9.3 (Area)	Samples are a mix of full-shift and short-term exposures.	Kiefer (1994)
Spray application of paints, coatings, and adhesives	Spray application of paints onto automotive seals	48 (PBZ) 20 (Area)	0.01 (PBZ) 0.01 (Area)	1.27 (PBZ) 25.0 (Area)	Individual data points not provided. Source only includes range and average of exposure values by job function.	NIOSH (1998)

PBZ – Personal Breathing Zone

B.3 Sources Containing Potentially Relevant Data or Information

Some sources of information and data related to releases and worker exposure were found during the Systematic review literature search. Sources of data or information identified in the Analysis Plan Sections 2.6.1.1 (releases) and 2.6.1.3 (occupational exposures) are shown in the four tables below. The data sources identified are based on preliminary results to date of the full-text screening step of the systematic review process. Further screening and quality evaluation are on-going. These sources will be reviewed to determine the utility of the data and information in the Risk Evaluation.

Table_Apx B-4. Potentially Relevant Data Sources for Information Related to Process Description

Bibliography	url
Nishimura, S., et al. (2009). "A cross-sectional observation of effect of exposure to N-methyl-2-pyrrolidone (NMP) on workers' health." Industrial Health **47**(4): 355-362.	Nishimura et al. (2009)
Solomon, G. M., et al. (1996). "Stillbirth after occupational exposure to N-methyl-2-pyrrolidone: A case report and review of the literature." Journal of Occupational and Environmental Medicine **38**(7): 705-713.	Solomon et al. (1996)
Bader, M., et al. (2006). "Ambient monitoring and biomonitoring of workers exposed to N-methyl-2-pyrrolidone in an industrial facility." International Archives of Occupational and Environmental Health **79**(5): 357-364.	Bader et al. (2006)
Meier, S., et al. (2013). "Biomonitoring of exposure to N-methyl-2-pyrrolidone in workers of the automobile industry." Annals of Occupational Hygiene **57**(6): 766-773.	Meier et al. (2013)
Muenter, J. and R. Blach (2010). "Ecological technology: NMP-free leather finishing." American Leather Chemists Association. Journal **105**(9): 303-308.	Muenter and Blach (2010)
Kim, B. R., et al. (2000). "Henry's law constants for paint solvents and their implications on volatile organic compound emissions from automotive painting." Water Environment Research **72**(1): 65-74.	Kim et al. (2000)
RIVM (2013). Annex XV Restriction Report: Proposal for a Restriction. RIVM, Bureau REACH. The Netherlands, National Institute for Public Health and the Environment (RIVM).	RIVM (2013)
OECD (2009). Emission scenario document on adhesive formulation. Paris, France.	OECD (2009a)
U.S. EPA (1998). Environmental profile for N-methylpyrrolidone. Washington, DC.	U.S. EPA (1998b)
ECHA (2014). Background document to the opinion on the annex XV dossier proposing restrictions on 1-methyl-2-pyrrolidone (NMP). Helsinki, Finland.	ECHA (2014a)
OECD (2017). Emission Scenario Document (ESD) on the use of textile dyes.	OECD (2017)
OECD (2015). Emission scenario document on use of adhesives. Paris, France.	OECD (2015)
OECD (2010). Emission Scenario Document on Formulation of Radiation Curable Coatings, Inks and Adhesives. Series on Emission Scenario Documents No. 21. Paris, OECD Environmental Health and Safety Publications.	OECD (2010a)
OECD (2010). Emission Scenario Document on Photoresist Use in Semiconductor Manufacturing. Series on Emission Scenario Documents No. 9. Paris, OECD Environmental Health and Safety Publications.	OECD (2010b)

OECD (2010). Scoping Document for Emission Scenario Document on Manufacturing and Use of Printing Inks, OECD Environmental Health and Safety Publications.	OECD (2010c)
OECD (2011). EMISSION SCENARIO DOCUMENT ON RADIATION CURABLE COATING, INKS AND ADHESIVES. Series on Emission Scenario Documents No. 27. Paris, OECD Environmental Health and Safety Publications.	OECD (2011)
White, D. L. and J. A. Bardole (2004). Paint and finish removers.	White and Bardole (2004)
(2017). PubChem: 1-Methyl-2-pyrrolidinone. Washington, DC, National Institute of Health, U.S. National Library of Medicine, National Center for Biotechnology Information.	NCBI (2017)
ECHA (2017). Uses as industrial sites: 1-Methyl-2-pyrrolidone. Helsinki, Finland.	ECHA (2017a)
ECHA (2017). Uses by professional workers: 1-Methyl-2-pyrrolidone. Helsinki, Finland.	ECHA (2017b)
NIOSH (2014). Health hazard evaluation report no. HHE-2011-0099-3211, evaluation of employee exposures during sea lamprey pesticide application. Cincinnati, OH.	NIOSH (2014a)
NICNAS (1997). Full public report: Polymer in byk-410.	NICNAS (1997)
NICNAS (2001). Full public report: Polymer in primal binder u-51.	NICNAS (2001)
NICNAS (1998). Full public report: Copolymer in foraperle 321.	NICNAS (1998)
Johnson Matthey Process Technologies (2017). "N-methyl-2-pyrrolidone (NMP)." from http://davyprotech.com/what-we-do/licensed-processes-and-core-technologies/licensed-processes/nmp/specification/.	Johnson Matthey Process Technologies (2017)
European Chemicals Agency (ECHA) (2016). 1-methyl-2-pyrrolidone brief profile.	European Chemicals Agency (ECHA) (2016)
BASF (1990). Technical information: N-methylpyrrolidone handling and storage. Parsippany, NJ.	BASF (1990)
TURI (1996). N-methyl pyrrolidone: Chemical profile. Lowell, MA, The Toxics Use Reduction Institute.	TURI (1996)
U.S. EPA (1998). Cleaner technologies substitutes assessment for professional fabricare processes: Appendix F: Chemical volume estimates: Screen printing CTSA. Washington, DC, Office of Pollution Prevention and Toxics.	U.S. EPA (1998a)

BASF (1993). Modification of a vapor degreasing machine for immersion cleaning use N-methylpyrrolidone. Parsippany, NJ.	BASF (1993)
BASF (1998). N-methylpyrrolidone(NMP): Biodegradability. Parsippany, NJ.	BASF (1998)
ERG (2000). Preferred and alternative methods for estimating air emissions from paint and ink manufacturing facilities. Durham, NC, Emission Inventory Improvement Program.	ERG (2000)
Technikon LLC (2001). Core box cleaner study: Evaporative emission study of specialty systems' solvent FC-47-G1. McClellan, CA, Casting Emission Reduction Program.	Technikon LLC (2001)
EC (2004). Effectiveness of vapour retardants in reducing risks to human health from paint strippers containing dichloromethane. Brussels, Belgium.	EC (2004a)
ERM (2017). Life cycle assessment of used oil management. London, UK.	ERM (2017)

Table_Apx B-5. Measured or Estimated Release Data

Bibliography	url
Kim, B. R., et al. (2000). "Henry's law constants for paint solvents and their implications on volatile organic compound emissions from automotive painting." Water Environment Research **72**(1): 65-74.	Kim et al. (2000)
OECD (2009). Emission scenario document on adhesive formulation. Paris, France.	OECD (2009a)
OECD (2017). Emission Scenario Document (ESD) on the use of textile dyes.	OECD (2017)
OECD (2015). Emission scenario document on use of adhesives. Paris, France.	OECD (2015)
OECD (2010). Emission Scenario Document on Formulation of Radiation Curable Coatings, Inks and Adhesives. Series on Emission Scenario Documents No. 21. Paris, OECD Environmental Health and Safety Publications.	OECD (2010a)
OECD (2010). Emission Scenario Document on Photoresist Use in Semiconductor Manufacturing. Series on Emission Scenario Documents No. 9. Paris, OECD Environmental Health and Safety Publications.	OECD (2010b)
OECD (2010). Scoping Document for Emission Scenario Document on Manufacturing and Use of Printing Inks, OECD Environmental Health and Safety Publications.	OECD (2010c)

OECD (2011). EMISSION SCENARIO DOCUMENT ON RADIATION CURABLE COATING, INKS AND ADHESIVES. Series on Emission Scenario Documents No. 27. Paris, OECD Environmental Health and Safety Publications.	OECD (2011)
(2016). Toxic release inventory: N-methyl-2-pyrrolidone.	U.S. EPA (2016c)
(2017). Hazardous substances data bank: 1-Methyl-2-pyrrolidinone. Rockville, MD, U.S. National Library of Medicine.	HSDB (2017)
ATSDR (2015). Health consultation: Review of air quality data: Intel Corporation – New Mexico facility: Rio Rancho, Sandoval County, New Mexico: EPA facility ID: NMD000609339, Part 2. Atlanta, GA, U.S. Department of Health and Human Services.	ATSDR (2015)
NICNAS (1997). Full public report: Polymer in byk-410.	NICNAS (1997)
NICNAS (2001). Full public report: Polymer in primal binder u-51.	NICNAS (2001)
NICNAS (1998). Full public report: Copolymer in foraperle 321.	NICNAS (1998)
BASF (1993). Modification of a vapor degreasing machine for immersion cleaning use N-methylpyrrolidone. Parsippany, NJ.	BASF (1993)
ERG (2000). Preferred and alternative methods for estimating air emissions from paint and ink manufacturing facilities. Durham, NC, Emission Inventory Improvement Program.	ERG (2000)
MO DNR (2001). State of Missouri toxics release inventory: Summary report: 1999 data. Jefferson City, MO, Technical Assistance Office.	MO DNR (2001)
Technikon LLC (2001). Core box cleaner study: Evaporative emission study of specialty systems' solvent FC-47-G1. McClellan, CA, Casting Emission Reduction Program.	Technikon LLC (2001)
Chemistry Industry Association of Canada (2017). All substances emissions for 2012 and projections for 2015. Ottawa, Canada.	Chemistry Industry Association of Canada (2017b)
Chemistry Industry Association of Canada (2017). All substances emissions for 2011 and projections for 2014. Ottawa, Canada.	Chemistry Industry Association of Canada (2017a)

Table_Apx B-6. Personal Exposure Monitoring and Area Monitoring Data

Bibliography	url
Nishimura, S., et al. (2009). "A cross-sectional observation of effect of exposure to N-methyl-2-pyrrolidone (NMP) on workers' health." Industrial Health **47**(4): 355-362.	Nishimura et al. (2009)
Haufroid, V., et al. (2014). "Biological monitoring and health effects of low-level exposure to N-methyl-2-pyrrolidone: a cross-sectional study." International Archives of Occupational and Environmental Health **87**(6): 663-674.	Haufroid et al. (2014)
Solomon, G. M., et al. (1996). "Stillbirth after occupational exposure to N-methyl-2-pyrrolidone: A case report and review of the literature." Journal of Occupational and Environmental Medicine **38**(7): 705-713.	Solomon et al. (1996)
Bader, M., et al. (2006). "Ambient monitoring and biomonitoring of workers exposed to N-methyl-2-pyrrolidone in an industrial facility." International Archives of Occupational and Environmental Health **79**(5): 357-364.	Bader et al. (2006)
Xiaofei, E., et al. (2000). "A linear pharmacokinetic model predicts usefulness of N-methyl-2-pyrrolidone (NMP) in plasma or urine as a biomarker for biological monitoring for NMP exposure." Journal of Occupational Health **42**(6): 321-327.	Xiaofei et al. (2000)
NICNAS (2013). Human health Tier II assessment for 2-pyrrolidinone, 1-methyl, CAS Number 872-50-4. N. I. C. N. Department of Health and S. Assessment.	NICNAS (2013)
RIVM (2013). Annex XV Restriction Report: Proposal for a Restriction. RIVM, Bureau REACH. The Netherlands, National Institute for Public Health and the Environment (RIVM).	RIVM (2013)
WHO (2001). Concise International Chemical Assessment Document 35: N-Methyl-2-Pyrrolidone. Geneva, Switzerland.	WHO (2001)
ECHA (2014). Background document to the opinion on the annex XV dossier proposing restrictions on 1-methyl-2-pyrrolidone (NMP). Helsinki, Finland.	ECHA (2014a)
NIOSH (2014). International chemical safety cards (ICDC): N-methyl-2-pyrrolidone. Atlanta, GA.	NIOSH (2014b)
OSHA (2017). Sampling and analytical methods: N-methyl-2-pyrrolidinone. Washington, DC, U.S. Department of Labor, Occupational Safety and Health Administration.	OSHA (2017b)
BASF (1993). Modification of a vapor degreasing machine for immersion cleaning use N-methylpyrrolidone. Parsippany, NJ.	BASF (1993)

OEHHA (2007). Occupational health hazard risk assessment project for California: Identification of chemicals of concern, possible risk assessment methods, and examples of health protective occupational air concentrations. Sacramento, CA.	OEHHA (2007)
EC (2007). Recommendation from the scientific committee on occupational exposure limits for n-methyl-2-pyrrolidone. Brussels, Belgium.	EC (2007b)
EU (2007). Impact assessment of potential restrictions on the marketing and use of dichloromethane in paint strippers. Revised final report-Annexes. Brussels, Belgium, European Commission, Directorate-General Enterprise and Industry.	EC (2007a)
EC (2004). Effectiveness of vapour retardants in reducing risks to human health from paint strippers containing dichloromethane. Brussels, Belgium.	EC (2004b)
IFA (2010). MEGA evaluations for the preparation of REACH exposure scenarios for N-methyl-2-pyrrolidone (vapor). Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA). July, 2010. http://www.dguv.de/medien/ifa/en/fac/reach/mega_auswertungen/n_methyl_2_pyrrolidon_en.pdf	IFA (2010)

Table_Apx B-7. Engineering Controls and Personal Protective Equipment

Bibliography	url
Nishimura, S., et al. (2009). "A cross-sectional observation of effect of exposure to N-methyl-2-pyrrolidone (NMP) on workers' health." Industrial Health **47**(4): 355-362.	Nishimura et al. (2009)
Bader, M., et al. (2006). "Ambient monitoring and biomonitoring of workers exposed to N-methyl-2-pyrrolidone in an industrial facility." International Archives of Occupational and Environmental Health **79**(5): 357-364.	Bader et al. (2006)
Meier, S., et al. (2013). "Biomonitoring of exposure to N-methyl-2-pyrrolidone in workers of the automobile industry." Annals of Occupational Hygiene **57**(6): 766-773.	Meier et al. (2013)
NICNAS (2013). Human health Tier II assessment for 2-pyrrolidinone, 1-methyl, CAS Number 872-50-4. N. I. C. N. Department of Health and S. Assessment.	NICNAS (2013)
OECD (2009). Emission scenario document on adhesive formulation. Paris, France.	OECD (2009a)
ECHA (2014). Background document to the opinion on the annex XV dossier proposing restrictions on 1-methyl-2-pyrrolidone (NMP). Helsinki, Finland.	ECHA (2014a)

OECD (2015). Emission scenario document on use of adhesives. Paris, France.	OECD (2015)
OECD (2010). Emission Scenario Document on Formulation of Radiation Curable Coatings, Inks and Adhesives. Series on Emission Scenario Documents No. 21. Paris, OECD Environmental Health and Safety Publications.	OECD (2010a)
OECD (2010). Emission Scenario Document on Photoresist Use in Semiconductor Manufacturing. Series on Emission Scenario Documents No. 9. Paris, OECD Environmental Health and Safety Publications.	OECD (2010b)
OECD (2011). EMISSION SCENARIO DOCUMENT ON RADIATION CURABLE COATING, INKS AND ADHESIVES. Series on Emission Scenario Documents No. 27. Paris, OECD Environmental Health and Safety Publications.	OECD (2011)
White, D. L. and J. A. Bardole (2004). Paint and finish removers.	White and Bardole (2004)
(2017). PubChem: 1-Methyl-2-pyrrolidinone. Washington, DC, National Institute of Health, U.S. National Library of Medicine, National Center for Biotechnology Information.	NCBI (2017)
(2017). Hazardous substances data bank: 1-Methyl-2-pyrrolidinone. Rockville, MD, U.S. National Library of Medicine.	HSDB (2017)
NIOSH (2014). Health hazard evaluation report no. HHE-2011-0099-3211, evaluation of employee exposures during sea lamprey pesticide application. Cincinnati, OH.	NIOSH (2014a)
NIOSH (2014). International chemical safety cards (ICDC): N-methyl-2-pyrrolidone. Atlanta, GA.	NIOSH (2014b)
NICNAS (1997). Full public report: Polymer in byk-410.	NICNAS (1997)
NICNAS (2001). Full public report: Polymer in primal binder u-51.	NICNAS (2001)
NICNAS (1998). Full public report: Copolymer in foraperle 321.	NICNAS (1998)
HESIS (2014). N-methylpyrrolidone (nmp): Health haazard advisory: Fact sheet. Richmond, CA.	HESIS (2014)

Appendix C SURFACE WATER ANALYSIS OF NMP RELEASES

This appendix provides an analysis of surface water concentrations based on reported surface water releases of NMP.

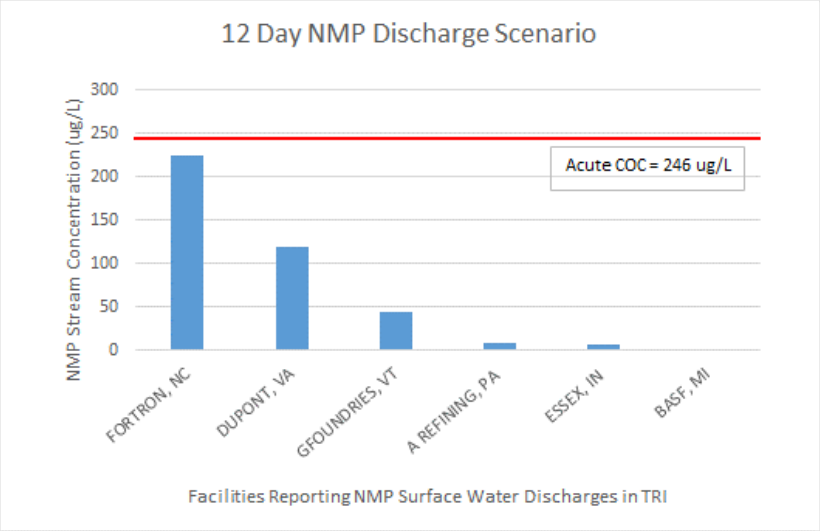
EPA considered several scenarios to estimate NMP concentrations in surface water resulting from industrial discharges. Using 2015 TRI available data and EPA's first-tier, Probabilistic Dilution Model (PDM) within the EPA Exposure and Fate Assessment Screening Tool (E-FAST), facilities with the largest releases of NMP were modeled for 12 days of release, and 250 days of release. The 12-day release scenario represents an acute scenario in which periodic maintenance and cleaning activities result in periodic releases. The 250-day scenario represents a chronic scenario in which operations consist of fairly constant discharges of NMP. Six facilities had reported direct discharges of NMP to surface waters and seven facilities reported indirect discharges, that is discharges sent to a municipal treatment facility also known as a public-owned treatment works (POTW) for treatment and discharge into surface waters. The single day release was considered the most conservative scenario since the NMP surface water concentrations were highest (see Table_Apx C-1).

Table_Apx C-1. Estimated NMP Surface Water Concentrations

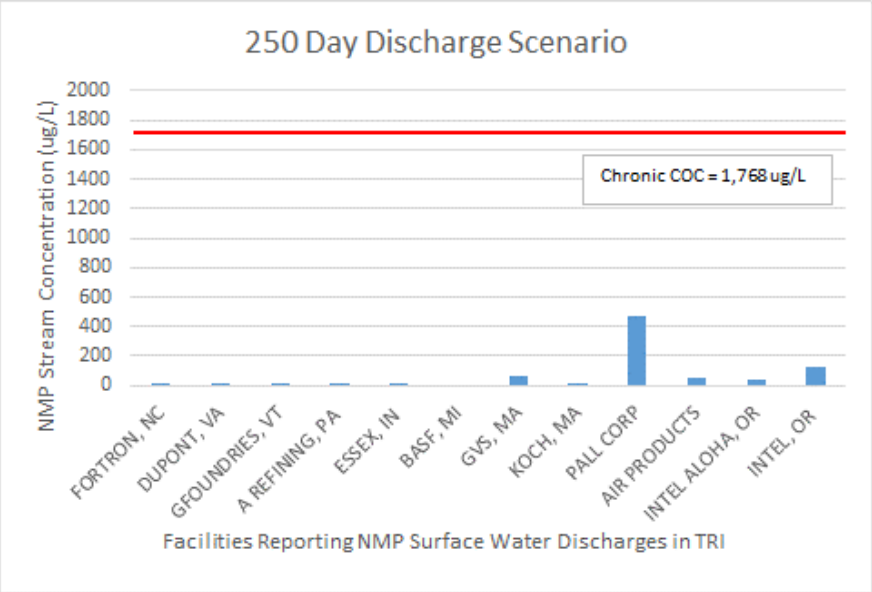
Top Facility Discharges (2015)		Direct TRI	Indirect TRI	PDM; input loadings (kg/site/day)		PDM; stream NMP concentrations	
Facility Location	State	Pounds (lbs/yr)	Pounds (lbs/yr)	12 day scenario	250 day scenario	12 day (ug/L)	250 day (ug/L)
WILMINGTON	NC	8,987	0	339.71	16.31	224.00	10.75
RICHMOND	VA	4,602	0	173.96	8.35	119.70	5.75
ESSEX JUNCTION	VT	451	0	17.05	0.82	44.49	2.14
BRADFORD	PA	26.83	0	1.01	0.05	8.49	0.4
FORT WAYNE	IN	22.1	0	0.84	0.04	5.56	0.27
WYANDOTTE	MI	2	21.52	0.08	0.00	0.0011	0.0000538
WESTBOROUGH	MA		8,048	304.21	14.60		69.03
WILMINGTON	MA		42,682	1613.38	77.44		4.79
PENSACOLA	FL		12,384	468.12	22.47		467.92
SAINT LOUIS	MO		12,001	453.64	21.77		50.86
ALOHA	OR		13,600	514.08	24.68		39.91
HILLSBORO	OR		40,800	1542.24	74.03		119.72

EPA then compared the surface water concentrations with the aquatic organism acute and chronic COCs estimated during problem formulation, 246 ppb and 1,768 ppb, respectively.

Figure_Apx C-1. Estimated Surface Water Concentration for 12-Day NMP Discharge



Figure_Apx C-2. Estimated Surface Water Concentration for 250 Day NMP Discharge



For all modeled NMP release scenarios, none of the facility discharges resulted in an exceedance of the acute or chronic levels of concern identified for ecological receptors.

Appendix D SUPPORTING TABLE FOR INDUSTRIAL AND COMMERCIAL ACTIVITIES AND USES CONCEPTUAL MODEL

Table_Apx D-1. Worker Exposure Conceptual Model Supporting Table (Note that rows shaded in gray are excluded from the scope of this risk evaluation)

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario		Exposure Pathway	Exposure Route	Receptor / Population	Further Analysis	Rationale for Further Analysis / no Further Analysis
Manufacture	Domestic Manufacture	Domestic Manufacture		Manufacture of NMP	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway. The number of sites manufacturing NMP is limited per CDR (11 sites).
					Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Mist / Dust	Dermal/Inhalation	Workers, ONU	No	Generation of mist and dust containing NMP is not expected during this operation.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario		Exposure Pathway	Exposure Route	Receptor / Population	Further Analysis	Rationale for Further Analysis / no Further Analysis
Manufacture	Import	Import		Repackaging of import containers	Liquid Contact	Dermal	Workers	Yes	Exposure expected only in the event the imported material is repackaged into different sized containers. Exposure frequency may be low. However, the number of workers potentially exposed may be high per CDR (13 submissions reporting <10 workers, 1 submission reporting 10 to 25 workers, 5 submissions reporting 50 to 100 workers, 1 submission reporting 100 to 500 workers, and 9 submissions claiming CBI or NKRA for number of workers).
					Vapor	Inhalation	Workers, ONU	Yes	Exposure expected only in the event the imported material is repackaged into different sized containers. EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Vapor	Dermal	Workers, ONU	Yes	Exposure expected only in the event the imported material is repackaged into different sized containers. NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Mist / Dust	Dermal/Inhalation	Workers, ONU	No	Generation of mist and dust containing NMP is not expected during this operation.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario		Exposure Pathway	Exposure Route	Receptor / Population	Further Analysis	Rationale for Further Analysis / no Further Analysis
Processing	Processing as a reactant or intermediate	Intermediate in Pharmaceutical and Medicine Manufacturing; Other Chemical Manufacturing		Pharmaceutical manufacturing; Chemical Manufacturing	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway. The number of workers potentially exposed may be high per CDR (1 submission reporting 500 to 1,000 workers and 1 submission reporting NKRA for number of workers).
					Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Mist / Dust	Dermal/Inhalation	Workers, ONU	No	Generation of mist and dust containing NMP is not expected during this operation.
Processing	Incorporated into formulation, mixture or reaction product	Adhesives and sealant chemicals in Adhesive Manufacturing; Anti-adhesive agents in Printing and Related Support Activities; Paint additives and coating additives not described by other codes in Paint and Coating Manufacturing; Print Ink Manufacturing; Plating agents and surface treating agents in Fabricated Metal Product Manufacturing; Solvents (for cleaning or degreasing) in Non-Metallic Mineral Product Manufacturing, Machinery Manufacturing, Plastic		Formulation of adhesives; Formulation of chemical mixtures; Formulation of paints, and coatings; Formulation of printing inks; Formulation of metal finishing chemicals; Formulation of cleaning and degreasing products; Formulation of cleaning fluids;	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway. The number of workers potentially exposed may be high per CDR (34 submissions reporting number of workers ranging from <10 to 500 to 1,000 workers).
					Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015).

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario		Exposure Pathway	Exposure Route	Receptor / Population	Further Analysis	Rationale for Further Analysis / no Further Analysis
		Material and Resin Manufacturing, Primary Metal Manufacturing, Soap, Cleaning Compound and Toilet Preparation Manufacturing, Transportation Equipment Manufacturing, All Other Chemical Product and Preparation Manufacturing, Printing and Related Support Activities, Services, Wholesale and Retail Trade; Solvents (which become part of product formulation or mixture) in Electrical Equipment, Appliance and Component Manufacturing, Other Manufacturing, Paint and Coating Manufacturing, Print Ink Manufacturing, Soap, Cleaning Compound and Toilet Preparation Manufacturing, Transportation Equipment Manufacturing, All Other Chemical Product and Preparation Manufacturing, Printing and Related Support Activities, Wholesale and Retail Trade; Surface active agents in Soap, Cleaning Compound and Toilet Preparation Manufacturing; Other uses in Oil and Gas Drilling, Extraction and Support Activities.		Formulation of petrochemical products					Vapor-through-skin is a pathway of concern.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Mist / Dust	Dermal/Inhalation	Workers, ONU	No	Generation of mist and dust containing NMP is not expected during this operation.
Processing	Incorporated into formulation, mixture or reaction product	Solvents (which become part of product formulation or mixture) in Other Manufacturing, All Other Chemical Product and Preparation Manufacturing.		Formulation of granular agricultural products	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway. The number of workers potentially exposed may be high per CDR (34 submissions reporting number of workers ranging from <10 to 500 to 1,000 workers).
					Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario		Exposure Pathway	Exposure Route	Receptor / Population	Further Analysis	Rationale for Further Analysis / no Further Analysis
									use due to the low volatility of NMP (VP = 0.345 mmHg).
					Dust	Inhalation	Workers, ONU	Yes	Dust formation is possible during manufacturing of solid products.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected during this operation.
Processing	Incorporated into article	Lubricants and lubricant additives in Machinery Manufacturing; Paint additives and coating additives not described by other codes in Transportation Equipment Manufacturing; Solvents (which become part of product formulation or mixture), including in Textiles, Apparel and Leather Manufacturing		Formulation of lubricants; Formulation of Paints and Coatings; Formulation of textile finishing chemicals	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway.
					Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Mist / Dust	Dermal/Inhalation	Workers, ONU	No	Generation of mist and dust containing NMP is not expected during this operation.
Processing	Incorporated into article	Other, including in Plastic Product Manufacturing		Plastics compounding	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario		Exposure Pathway	Exposure Route	Receptor / Population	Further Analysis	Rationale for Further Analysis / no Further Analysis
				and Plastics converting	Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Dust	Inhalation	Workers, ONU	Yes	Dust formation is possible during plastic processing activities.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Mist	Dermal/Inhalation	Workers, ONU	No	Mist generation not expected during this operation.
Processing	Repackaging	Wholesale and Retail Trade		Repackaging into large and small containers	Liquid Contact	Dermal	Workers	Yes	Low ranking - screening-level analysis will be done
					Vapor	Inhalation	Workers, ONU	Yes	Low ranking - screening-level analysis will be done
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Mist / Dust	Dermal/Inhalation	Workers, ONU	No	Generation of mist and dust containing NMP is not expected during this operation.
Processing	Recycling	Recycling			Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario		Exposure Pathway	Exposure Route	Receptor / Population	Further Analysis	Rationale for Further Analysis / no Further Analysis
				Recycling of process solvents containing NMP	Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Mist / Dust	Dermal/Inhalation	Workers, ONU	No	Generation of mist and dust containing NMP is not expected during this operation.
Distribution in commerce	Distribution	Distribution		Distribution of bulk shipments of NMP; Distribution of formulated products	Liquid Contact, Vapor / Dust	Dermal/ Inhalation	Workers, ONU	No	Low priority for assessment. Exposure will only occur in the event of spills.
Industrial, commercial, and consumer use	Paints and coatings; Paint additives and coating additives not described by other codes; Adhesives and sealants	Adhesive and paint and coating removers; Lacquers, stains, varnishes, primers and floor finishes; Powder coatings (surface preparation); Paint and Coating Use in Computer and Electronic Product Manufacturing, Construction, Fabricated Metal Product Manufacturing, Machinery Manufacturing, Other Manufacturing, Paint and Coating Manufacturing, Primary Metal		Adhesive and paint and coating removal by contractors; Roll/curtain application and spray application of paints, coatings, adhesives, and sealants and removers	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway. The number of workers potentially exposed may be high per CDR (16 submissions reporting the number of workers ranging from <10 workers to >10,000 workers).
					Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Mist	Inhalation	Workers, ONU	Yes	Mist generation is expected to occur during this operation.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario		Exposure Pathway	Exposure Route	Receptor / Population	Further Analysis	Rationale for Further Analysis / no Further Analysis
		Manufacturing, Transportation Equipment Manufacturing, Wholesale and Retail Trade; Adhesives and sealant chemicals including binding agents; Single component glues and adhesives, including lubricant adhesives; Two-component glues and adhesives, including some resins			Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Dust	Dermal/Inhalation	Workers, ONU	No	Generation of dust containing NMP is not expected during this operation.
Industrial, commercial, and consumer use	Paints and coatings; Paint additives and coating additives not described by other codes; Adhesives and sealants	Lacquers, stains, varnishes, primers and floor finishes; Powder coatings (surface preparation); Paint and Coating Use in Computer and Electronic Product Manufacturing, Construction, Fabricated Metal Product Manufacturing, Machinery Manufacturing, Other Manufacturing, Paint and Coating Manufacturing, Primary Metal Manufacturing, Transportation Equipment Manufacturing, Wholesale and Retail Trade; Adhesives and sealant chemicals including binding agents; Single component glues and adhesives, including lubricant adhesives; Two-component glues and adhesives, including some resins		Manual (roller/brush) application and syringe/bead application of paints, coatings, adhesives, and sealants and removers	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway. The number of workers potentially exposed may be high per CDR (16 submissions reporting the number of workers ranging from <10 workers to >10,000 workers).
					Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Mist / Dust	Dermal/Inhalation	Workers, ONU	No	Generation of mist and dust containing NMP is not expected during this operation.
Industrial, commercial,				Aerosol degreasing	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario		Exposure Pathway	Exposure Route	Receptor / Population	Further Analysis	Rationale for Further Analysis / no Further Analysis
and consumer use	Solvents (for cleaning or degreasing)	Use in Electrical Equipment, Appliance and Component Manufacturing			Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Mist	Inhalation	Workers, ONU	Yes	Mist generation is expected to occur during this operation.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Dust	Dermal/Inhalation	Workers, ONU	No	Generation of dust containing NMP is not expected during this operation.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario		Exposure Pathway	Exposure Route	Receptor / Population	Further Analysis	Rationale for Further Analysis / no Further Analysis
Industrial, commercial, and consumer use	Solvents (for cleaning or degreasing)	Use in Electrical Equipment, Appliance and Component Manufacturing		Wipe cleaning	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway.
					Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Mist / Dust	Dermal/Inhalation	Workers, ONU	No	Generation of mist and dust containing NMP is not expected during this operation.
Industrial, commercial, and consumer use	Ink, toner and colorant products	Printer ink		Industrial / commercial printing	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway. The number of workers is limited per CDR (1 submission reporting <10 workers and 1 submission reporting 100 to 500 workers).
					Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario		Exposure Pathway	Exposure Route	Receptor / Population	Further Analysis	Rationale for Further Analysis / no Further Analysis
					Mist / Dust	Dermal/Inhalation	Workers, ONU	No	Generation of mist and dust containing NMP is not expected during this operation.
Industrial, commercial, and consumer use	Processing aids, specific to petroleum production	Petrochemical Manufacturing		Oil and gas extraction; Petrochemical purifications	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway. The number of workers potentially exposed is limited per CDR (1 submission reporting 50 to 100 workers and 2 submissions reporting NKRA for number of workers).
					Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Mist / Dust	Dermal/Inhalation	Workers, ONU	No	Generation of mist and dust containing NMP is not expected during this operation.
Industrial, commercial, and consumer use	Adhesives and sealants	Soldering materials		Industrial and commercial soldering	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway. The number of workers potenitally exposed is limited per CDR (1 submission reporting 50 to 100 workers and 2 submissions reporting NKRA for number of workers).
					Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario		Exposure Pathway	Exposure Route	Receptor / Population	Further Analysis	Rationale for Further Analysis / no Further Analysis
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Mist / Dust	Dermal/Inhalation	Workers, ONU	Yes	EPA will further evaluate to determine if mist and dust generation is applicable.
Industrial, commercial, and consumer use	Other uses	Other non-aerosol uses, e.g. anti-freeze and de-icing products; automotive care products; lubricants and greases; Lubricant and lubricant additives, including hydrophilic coatings; Metal products not covered elsewhere; Laboratory chemicals; Lithium ion batteries; Cleaning and furniture care products, including wood cleaners, gasket removers; Pharmaceutical and Medicine Manufacturing - functional fluids (closed systems); Wood preservatives		Commercial automotive servicing, including application of lubricants; Manual (brushing) and dip application of metal finishing products; Laboratory use; Industrial battery use; Wipe cleaning; Pharmaceutical chemical extractions; Manual (paste/brush) application of wood preservatives	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway. However, the potential for exposure is unknown where NMP is incorporated into articles.
					Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Mist / Dust	Dermal/Inhalation	Workers, ONU	No	Generation of mist and dust containing NMP is not expected during this operation.
Industrial, commercial,	Other uses	Other aerosol uses, e.g. metal products not covered		Spray application of	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario		Exposure Pathway	Exposure Route	Receptor / Population	Further Analysis	Rationale for Further Analysis / no Further Analysis
and consumer use		elsewhere; Cleaning and furniture care products, including wood cleaners, gasket removers; Fertilizer and other agricultural chemical manufacturing - processing aids and solvents		metal finishing products; Spray/aerosol application of cleaning products; Commercial fertilizer application	Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Mist	Inhalation	Workers, ONU	Yes	Mist generation is expected to occur during this operation.
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.
					Dust	Dermal/Inhalation	Workers, ONU	No	Chemical is not expected to be in solid form.
Disposal	Waste Handling, Treatment and Disposal	Disposal of NMP wastes		Worker handling and disposal of waste	Liquid Contact	Dermal	Workers	Yes	Dermal exposure is expected to be a primary pathway. Frequency of exposure and the potential for dermal immersion needs to be evaluated.
					Vapor	Inhalation	Workers, ONU	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
					Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
					Vapor	Dermal	Workers, ONU	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015). Vapor-through-skin is a pathway of concern.

Appendix E SUPPORTING TABLE FOR CONSUMER ACTIVITES AND USES CONCEPTUAL MODEL

Table_Apx E-1. Supporting Table for Consumer Activities and Uses Conceptual Model

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
Consumer Use	Paints and Coatings	Paint and coating removers	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Paints and Coatings	Paint and coating removers	Spray Application	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
Consumer Use	Paints and Coatings	Paint and coating removers	Spray Application	Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Paints and Coatings	Adhesive removers	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Paints and Coatings	Adhesive removers	Spray Application	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Paints and Coatings	Lacquers, stains, varnishes, primers and floor finishes	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Vapor/Mist	Inhalation	Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
Consumer Use	Paints and Coatings	Lacquers, stains, varnishes, primers and floor finishes	Spray Application	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Paint additives and coating additives	Construction; Wholesale and Retail Trade	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Paint additives and coating additives	Construction; Wholesale and Retail Trade	Spray Application	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Solvents (for cleaning and degreasing)	Use in Electrical Equipment, Appliance and Component Manufacturing	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
Consumer Use	Solvents (for cleaning and degreasing)	Use in Electrical Equipment, Appliance and Component Manufacturing	Spray Application	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Ink, toner and colorant products	Printer ink	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Ink, toner and colorant products	Inks in writing equipement	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
Consumer Use	Adhesives and sealants	Adhesives and sealant chemicals including binding agents	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Adhesives and sealants	Adhesives and sealant chemicals including binding agents	Spray Application	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Adhesives and sealants	Single component glues and adhesives, including lubricant adhesives	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Adhesives and sealants	Single component glues and	Spray Application	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
		adhesives, including lubricant adhesives		Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Adhesives and sealants	Two-component glues and adhesives, including some resins	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Adhesives and sealants	Soldering materials	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Other uses	Automotive care products	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Other uses	Automotive care products	Spray Application	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
Consumer Use	Other uses	Lubricants and greases	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Other uses	Lubricants and greases	Spray Application	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
								certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Other uses	Cleaning and furniture care products, including wood cleaners, gasket removers	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Other uses	Cleaning and furniture care products,	Spray Application	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
		including wood cleaners, gasket removers		Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Other uses	Lubricant and lubricant additives, including hydrophilic coatings	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Other uses	Lubricant and lubricant additives, including hydrophilic coatings	Spray Application	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Other uses	Wood preservatives	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Other uses	Wood preservatives	Spray Application	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
Consumer Use	Other uses	Arts and Crafts, Hobby Materials	Evaporation from surface	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Other uses	Arts and Crafts, Hobby Materials	Spray Application	Liquid contact	Dermal	Consumers	Yes	Dermal exposure is expected to be a primary pathway since NMP is well absorbed following dermal exposures.
				Vapor through skin	Dermal	Consumers/ Bystanders	Yes	NMP is well absorbed following dermal exposures and dermal absorption including NMP from the vapor phase typically contributes significantly to human exposure (U.S. EPA, 2015a). Vapor-through-skin is a pathway of concern.
				Liquid contact	Oral	Consumers	Yes	NMP contamination of hands resulting from product use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be low.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Routes	Receptor	Proposed for Further Analysis	Rationale for Further Analysis/ No Further Analysis
				Vapor/Mist	Inhalation	Consumers/ Bystanders	Yes	EPA will further evaluate vapor generation potential, as inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP (VP = 0.345 mmHg).
				Liquid contact	Dermal	Bystanders	No	Bystanders are not expected to have direct contact with liquids containing NMP
				Liquid contact	Oral	Bystanders	Yes	NMP contamination of hands resulting from near-field use may result in consumer exposure to NMP via ingestion. NMP exposure via oral route is expected to be unlikely for bystanders.
Consumer Use	Other uses	Articles	Children's soft toys, blankets, etc	Liquid contact	Dermal	Consumers (Children)	Yes	Residual NMP in article could be source of dermal exposure. NMP is well absorbed following dermal exposures.
				Liquid contact	Oral (mouthing)	Consumers (Children)	Yes	Residual NMP in article could be source of exposure due to children's mouthing behavior.

Appendix F SUPPORTING TABLE FOR ENVIRONMENTAL RELEASES AND WASTES CONCEPTUAL MODEL

Table_Apx F-1. Supporting Table for Environmental Releases and Wastes Conceptual Model

Life Cycle Stage	Release	Exposure Pathway/ Media	Exposure Routes	Receptor / Population	Further Analysis?	Rationale for Further Analysis/ No Further Analysis
Disposal	Industrial wastewater treatment operations	Direct release into surface water	Surface water	Aquatic Species	No	Conservative Tier 1 screening indicates low risk concern for aquatic organisms (see section 2.3.4)
				Terrestrial Species	No	Conservative Tier 1 screening indicates low concentrations of NMP in surface water. Ingestion of water is not expected to be a significant route of NMP exposure for terrestrial organisms.
	Industrial wastewater treatment operations	Direct release into surface water and indirect partitioning to sediment	Sediment	Aquatic Species	No	NMP has low sorption to soil, sludge, and sediment (log Koc = 0.9) and will instead stay in the associated aqueous phases due to high water solubility (1,000 g/L).
				Terrestrial Species	No	
Disposal	Industrial pre-treatment, then transfer to Publicly Owned Treatment Works (POTW)	Direct release into surface water	Surface water	Aquatic Species	No	Conservative Tier 1 screening indicates low risk concern for aquatic organisms (see section 2.3.4)
				Terrestrial Species	No	NMP exposure via ingestion of water and inhalation of air are expected to present a low risk concern for terrestrial organisms.
Disposal	Industrial pre-treatment, then transfer to Publicly Owned Treatment Works (POTW)	Direct release into surface water and indirect partitioning to sediment	Sediment	Aquatic Species	No	NMP has low sorption to soil, sludge, and sediment (log Koc = 0.9) and will instead stay in the associated aqueous phases (solubility = 1,000 g/L).
Disposal	Industrial pre-treatment, then transfer to Publicly Owned Treatment Works (POTW)	Direct release into surface water and indirect partitioning to sediment	Sediment	Terrestrial Species	No	Based on physical-chemical properties (log Koc = 0.9), NMP is not expected to partition to soil, sludge, and sediment. NMP is expected to remain in the aqueous phase (water solubility = 1,000 g/L).

Life Cycle Stage	Release	Exposure Pathway/ Media	Exposure Routes	Receptor / Population	Further Analysis?	Rationale for Further Analysis/ No Further Analysis
Disposal	Biosolids and land disposal to soil	Migration from biosolids via soil deposition	Soil	Terrestrial Species	No	Due to NMP's physical-chemical properties, (log Koc = 0.9, and water solubility = 1,000 g/L), NMP is not expected to partition to soil; aerobic biodegradation and mobility in soil are expected to limit accumulation in this environmental compartment.
			Groundwater - Ingestion	General Population: Adults and children living near facilities	No	Conservative Tier 1 screening indicates low concentrations of NMP in surface water. NMP releases from land application of biosolids are expected to be much less than those associated with direct release of wastewater treatment plant effluents to surface water.
All	Emissions to Air	Near facility ambient air concentrations	Inhalation	General Population: Adults and children living near facilities	No	Conservative Tier 1 screening indicates low risk concern to general population (see section 2.5.3.1)
		Indirect deposition to nearby bodies of water and soil catchments	Soil	Terrestrial Species	No	NMP is not expected to remain in soil for long periods of time due to aerobic biodegradation and migration to groundwater due to the log Koc (0.9) and water solubility (1,000 g/L).

Appendix G INCLUSION AND EXCLUSION CRITERIA FOR FULL TEXT SCREENING

Appendix G contains the eligibility criteria for various data streams informing the TSCA risk evaluation: environmental fate; engineering and occupational exposure; exposure to consumers; and human health hazard. The criteria are applied to the *on-topic* references that were identified following title and abstract screening of the comprehensive search results published on June 22, 2017.

Systematic reviews typically describe the study eligibility criteria in the form of PECO statements or a modified framework. PECO stands for Population, Exposure, Comparator and Outcome and the approach is used to formulate explicit and detailed criteria about those characteristics in the publication that should be present in order to be eligible for inclusion in the review. EPA/OPPT adopted the PECO approach to guide the inclusion/exclusion decisions during full text screening.

Inclusion and exclusion criteria were also used during the title and abstract screening, and documentation about the criteria can be found in the *Strategy for Conducting Literature Searches* document published in June 2017 along with each of the TSCA Scope documents. The list of *on-topic* references resulting from the title and abstract screening is undergoing full text screening using the criteria in the PECO statements. The overall objective of the screening process is to select the most relevant evidence for the TSCA risk evaluation. As a general rule, EPA is excluding non-English data/information sources and will translate on a case by case basis.

The inclusion and exclusion criteria for ecotoxicological data have been documented in the ECOTOX SOPs. The criteria can be found at https://cfpub.epa.gov/ecotox/help.cfm?helptabs=tab4) and in the *Strategy for Conducting Literature Searches* document published along with each of the TSCA Scope documents.

G.1 Inclusion Criteria for Data Sources Reporting Environmental Fate Data

EPA/OPPT developed a generic PESO statement to guide the full text screening of environmental fate data sources. PESO stands for Pathways and Processes, Exposure, Setting or Scenario, and Outcomes. Subsequent versions of the PESO statement may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria in the PESO statement are eligible for inclusion, considered for evaluation, and possibly included in the environmental fate assessment. On the other hand, data sources are excluded if they do not meet the criteria in the PESO statement.

Assessors seek information on various chemical-specific fate endpoints and associated fate processes, environmental media and exposure pathways as part of the process of developing the environmental fate assessment.

G.2 Inclusion Criteria for Data Sources Reporting Releases and Occupational Exposure Data

EPA/OPPT developed a generic RESO statement to guide the full text screening of releases and occupational exposure literature (Table_Apx G1). RESO stands for Receptors, Exposure, Setting or Scenario, and Outcomes. Subsequent versions of the RESO statement may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria specified in the RESO statement will be eligible for inclusion, considered for evaluation, and possibly included in the environmental release and occupational exposure assessments, while those that do not meet these criteria will be excluded.

The RESO statement should be used along with the engineering, release and occupational exposure data needs table (Table_Apx G2) when screening the literature.

Since full text screening commenced right after the publication of the TSCA Scope document, the criteria for engineering and occupational exposure data were set to be broad to capture relevant information that would support the risk evaluation. Thus, the inclusion and exclusion criteria for full text screening do not reflect the refinements to the conceptual model and analysis plan resulting from problem formulation. As part of the iterative process, EPA is in the process of refining the results of the full text screening to incorporate the changes in information/data needs to support the risk evaluation.

Table_Apx G-1. Inclusion Criteria for Data Sources Reporting Release and Occupational Exposure Data

RESO Element	**Evidence**
Receptors	• **Humans:** Workers, including occupational non-users Please refer to the conceptual models for more information about the ecological and human receptors included in the TSCA risk evaluation.
Exposure	• Worker exposure to and relevant occupational environmental releases of the chemical substance of interest ○ Dermal and inhalation exposure routes (as indicated in the conceptual model) Please refer to the conceptual models for more information about the routes and media/pathways included in the TSCA risk evaluation.
Setting or **S**cenario	• Any occupational setting or scenario resulting in worker exposure and environmental releases (includes all manufacturing, processing, use, disposal indicated in Table_Apx G below.
Outcomes	• Quantitative estimates* of worker exposures and of relevant environmental releases from occupational settings • General information and data related and relevant to the occupational estimates*

* Metrics (e.g., mg/kg/day or mg/m^3 for worker exposures, kg/site/day for releases) are determined by toxicologists for worker exposures and by exposure assessors for releases; also, the Engineering, Release, and Occupational Exposure Data Needs (Table_Apx G2) provides a list of related and relevant general information.
TSCA=Toxic Substances Control Act

Table_Apx G-2. Engineering, Environmental Release and Occupational Data Necessary to Develop the Environmental Release and Occupational Exposure Assessments

Objective Determined during Scoping	Type of Data
General Engineering Assessment (may apply for either or both Occupational Exposures and / or Environmental Releases)	1. Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (e.g., each manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages. {Tags: Life cycle description, Life cycle diagram} [a] 2. The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step. {Tags: Production volume, Import volume, Use volume, Percent PV} [a] 3. Description of processes, equipment, unit operations, and material flows and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the chemical of interest and material flows of all associated primary chemicals (especially water). {Tags: Process description, Process material flow rate, Annual operating days, Annual batches, Weight fractions (for each of above, manufacture, import, processing, use)} [a] 4. Basic chemical properties relevant for assessing exposures and releases, e.g., molecular weight, normal boiling point, melting point, physical form, and room temperature vapor pressure. {Tags: Molecular weight, Boiling point, Melting point, Physical form, Vapor pressure, Water solubility} [a] 5. Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/ commercial life cycle step and site location. {Tags: Numbers of sites (manufacture, import, processing, use), Site locations} [a]
Occupational Exposures	6. Description of worker activities with exposure potential during the manufacture, processing, or use of the chemical(s) of interest in each industrial/commercial life cycle stage. {Tags: Worker activities (manufacture, import, processing, use)} [a] 7. Potential routes of exposure (e.g., inhalation, dermal). {Tags: Routes of exposure (manufacture, import, processing, use)} [a] 8. Physical form of the chemical(s) of interest for each exposure route (e.g., liquid, vapor, mist) and activity. {Tags: Physical form during worker activities (manufacture, import, processing, use)} [a] 9. Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted average (TWA), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage). {Tags: PBZ measurements (manufacture, import, processing, use)} [a] 10. Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage of interest). {Tags: Area measurements (manufacture, import, processing, use)} [a] 11. For solids, bulk and dust particle size distribution (PSD) data. {Tags: PSD measurements (manufacture, import, processing, use)} [a] 12. Dermal exposure data. {Tags: Dermal measurements (manufacture, import, processing, use)} Data needs associated with mathematical modeling (will be determined on a case-by-case basis). {Tags: Worker exposure modeling data needs (manufacture, import, processing, use)} [a] 13. Exposure duration (hrs/day). {Tags: Worker exposure durations (manufacture, import, processing, use)} [a] 14. Exposure frequency (days/yr). {Tags: Worker exposure frequencies (manufacture, import, processing, use)} [a] 15. Number of workers who potentially handle or have exposure to the chemical(s) of interest in each life cycle stage. {Tags: Numbers of workers exposed (manufacture, import, processing, use)} [a] 16. Personal protective equipment (PPE) types employed by industries within the scope. {Tags: Worker PPE (manufacture, import, processing, use)} [a] 17. Engineering controls employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage of interest), and associated data or estimates of exposure reductions. {Tags: Engineering controls (manufacture, import, processing, use), Engineering control effectiveness data} [a]

Environmental Releases (to relevant environmental media)	18. Description of sources of potential environmental releases, including cleaning of residues from process equipment and transport containers involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage. {Tags: Release sources (manufacture, import, processing, use)} [a] 19. Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to each environmental medium (water) and treatment and disposal methods (POTW), including releases per site and aggregated over all sites (annual release rates, daily release rates) {Tags: Release rates (manufacture, import, processing, use)} [a] 20. Release or emission factors. {Tags: Emission factors (manufacture, import, processing, use)} [a] 21. Number of release days per year. {Tags: Release frequencies (manufacture, import, processing, use)} [a] 22. Data needs associated with mathematical modeling (will be determined on a case-by-case basis). {Tags: Release modeling data needs (manufacture, import, processing, use)} [a] 23. Waste treatment methods and pollution control devices employed by the industries within scope and associated data on release/emission reductions. {Tags: Treatment/ emission controls (manufacture, import, processing, use), Treatment/ emission controls removal/ effectiveness data} [a]

Notes:

[a] These are the tags included in the full text screening form. The screener makes a selection from these specific tags, which describe more specific types of data or information.

Abbreviations:

hr = Hour
kg = Kilogram(s)
lb = Pound(s)
yr = Year
PV = Production volume
PBZ = Personal breathing zone
POTW = Publicly owned treatment works
PPE = Personal protective equipment
PSD = Particle size distribution
TWA = Time-weighted average

G.3 Inclusion Criteria for Data Sources Reporting Exposure Data on Consumers and Ecological Receptors

EPA/OPPT developed PECO statements to guide the full text screening of exposure data/information for human (i.e., consumers, potentially exposed or susceptible subpopulations) and ecological receptors. Subsequent versions of the PECO statements may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria in the PECO statement are eligible for inclusion, considered for evaluation, and possibly included in the exposure assessment. On the other hand, data sources are excluded if they do not meet the criteria in the PECO statement. The NMP-specific PECO is provided in Table_Apx G1 thru Table_Apx G4.

Since full text screening commenced right after the publication of the TSCA Scope document, the criteria for exposure data were set to be broad to capture relevant information that would support the risk evaluation. Thus, the inclusion and exclusion criteria for full text screening do not reflect the refinements to the conceptual model and analysis plan resulting from problem formulation. As part of the iterative process, EPA is in the process of refining the results of the full text screening to incorporate the changes in information/data needs to support the risk evaluation.

Table_Apx G-3. Inclusion Criteria for the Data Sources Reporting N-Methylpyrrolidone Exposure Data on Consumers and Ecological Receptors

PECO Element	Evidence
Population	**Human:** Consumers (i.e., individuals who use a product directly) and bystanders (i.e., those individuals who happen to be in close proximity during use of NMP-containing products), including, susceptible populations (e.g., lifestages, preexisting conditions, genetic factors), such as infants, children, pregnant women, women of child bearing age; do-it-yourself (DIY) or high-end consumers.
	Ecological: Aquatic and terrestrial biota (organisms and plants).
Exposure	**Expected Primary Exposure Sources, Pathways, Routes** **Sources:** Consumer uses in the home producing releases of NMP to air and dermal contact; industrial and commercial activities that generate releases to surface water; NMP remaining primarily in aqueous media of biosolids after wastewater treatment. **Pathways**: Indoor/outdoor air and dermal contact with NMP in consumer products (e.g., liquid contact), vapor/mist/dust, dust; biosolids application to soil. **Routes**: oral (dust or by mouthing), inhalation (vapor/mist), dermal (liquid contact); dermal (vapor to skin).
Comparator (Scenario)	**Human:** Consider media-specific background exposure scenarios and use/source-specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
	Ecological: Aquatic and terrestrial species exposure via contact with or ingestion of surface water; terrestrial species exposure via contact with soil.

PECO Element	Evidence
Outcomes for Exposure Concentration or Dose	**Human:** Acute, subchronic, and/or chronic external exposure dose estimates (mg/kg/day); acute, subchronic, and/or chronic air concentration estimates (mg/m^3 or mg/L). Both external potential dose and internal dose based on biomonitoring and reverse dosimetry mg/kg/day will be considered.
	Ecological: A range of ecological receptors will be considered using surface water concentrations, sediment concentrations, and soil concentrations.

Abbreviations:
NMP = N-Methylpyrrolidone

G.4 Inclusion Criteria for Data Sources Reporting Human Health Hazards

EPA/OPPT developed chemical-specific PECO statements Table_Apx G1 thru Table_Apx G4) to guide the full text screening of the human health hazard literature. Subsequent versions of the PECOs may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the criteria specified in the PECO statement will be eligible for inclusion, considered for evaluation, and possibly included in the human health hazard assessment, while those that do not meet these criteria will be excluded according to the exclusion criteria.

In general, the PECO statements were based on (1) information accompanying the TSCA Scope document, and (2) preliminary review of the health effects literature from authoritative sources cited in the TSCA Scope documents. When applicable, these authoritative sources (e.g., IRIS assessments, EPA/OPPT's Work Plan problem formulations or risk assessments) will serve as starting points to identify PECO-relevant studies.

Table_Apx G-4. Inclusion Criteria for Data Sources Reporting Human Health Hazards Related to N-Methylpyrrolidone (NMP) [a]

PECO Element	Evidence Stream	Papers/Features Included	Papers/Features Excluded

Population [b]	*Human*	• Any population
		• All lifestages
		• Study designs:
		  ○ Controlled exposure, cohort, case-control, cross-sectional, case-crossover
		  ○ Case studies and case series that are related to deaths from acute exposure
			• Case studies and case series for all endpoints ***other than*** death from acute exposure

	Animal	• All non-human whole-organism mammalian species • All lifestages	• Non-mammalian species
Exposure	*Human*	• Exposure based on administered dose or concentration of NMP, biomonitoring data (e.g., urine, blood or other specimens), environmental or occupational-setting monitoring data (e.g., air, water levels), job title or residence • Primary metabolites of interest as identified in biomonitoring studies (5-hydroxy-N-methyl-2-pyrrolidone (5-HNMP) and 2-hydroxy-N-methylsuccinimide (2-HMSI)) • Exposure identified as ***or presumed to be*** from oral, dermal, inhalation routes • Any number of exposure groups • Quantitative, semi-quantitative or qualitative estimates of exposure • Exposures to multiple chemicals/mixtures only if NMP or related metabolites were independently measured and analyzed	• Route of exposure ***not*** by inhalation, oral or dermal type (e.g., intraperitoneal, injection) • Multiple chemical/mixture exposures with no independent measurement of or exposure to NMP (or related metabolite)

PECO Element	Evidence Stream	Papers/Features Included	Papers/Features Excluded
	Animal	• A minimum of 2 quantitative dose or concentration levels of NMP plus a negative control group[a] • Acute, subchronic, chronic exposure from oral, dermal, inhalation routes • Exposure to NMP only (no chemical mixtures) • Quantitative or semi-quantitative estimates of exposure are included	• Only 1 quantitative dose or concentration level in addition to the control • Route of exposure ***not*** by inhalation, oral or dermal type (e.g., intraperitoneal, injection) • No duration of exposure stated • Exposure to NMP in a chemical mixture
Comparator	*Human*	• A comparison population [not exposed, exposed to lower levels, exposed below detection] for endpoints ***other than*** death from acute exposure	• No comparison population for endpoints other than death from acute exposure
	Animal	• Negative controls that are vehicle-only treatment and/or no treatment	• Negative controls ***other than*** vehicle-only treatment or no treatment
Outcome	*Human*	• Endpoints described in the NMP scope document [c]: o Acute toxicity (neurotoxicity and lethality) o Reproductive toxicity o Growth (early life) and developmental toxicity o Immunotoxicity o Neurotoxicity o Irritation • Other endpoints [d]	
	Animal		
General Considerations		**Papers/Features Included**	**Papers/Features Excluded**
		• Written in English [e] • Reports primary data • Full text available • Reports both NMP exposure ***and*** a health outcome	• Not written in English • Reports secondary data (e.g., review papers) [a] • No full text available (e.g., only a study description/abstract, out-of-print text) • Reports NMP-related exposure ***or*** a health outcome, but not both (e.g. incidence, prevalence report)

[a] Some of the studies that are excluded based on the PECO statement may be considered later during the systematic review process. For NMP, EPA will evaluate studies related to susceptibility and may evaluate, toxicokinetics and physiologically based pharmacokinetic models after other data (e.g., human and animal data identifying adverse health outcomes) are reviewed. EPA may need to evaluate mechanistic data depending on the review of health effects data. Finally, EPA may also review other data as needed (e.g., animal studies using one concentration, review papers).

[b] Mechanistic data are excluded during the full text screening phase of the systematic review process but may be considered later (see footnote *a*).

[c] EPA will review key and supporting studies in EPA's 2015 Work Plan Chemical Risk Assessment for non-cancer and cancer endpoints as well as studies published after the assessment.

[d] EPA may screen for hazards other than those listed in the scope document if they were identified in the updated literature search that accompanied the scope document.

[e] EPA may translate studies as needed.

Abbreviations: NMP= N-Methylpyrrolidone