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United States
Environmental Protection Agency

Scope of the Risk Evaluation for N-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-)

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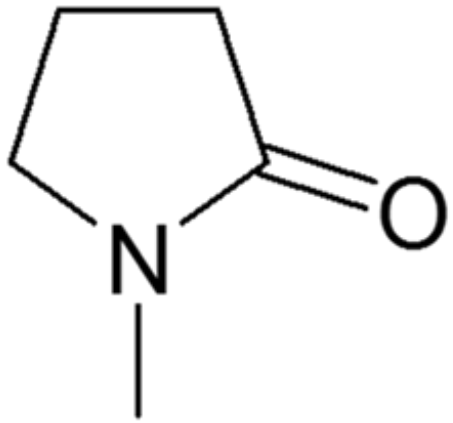

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ABBREVIATIONS

°C	Degrees Celsius
AIHA	American Industrial Hygiene Association
AQS	Air Quality System
atm	Atmosphere(s)
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BSER	Best System of Emission Reduction
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
CHIRP	Chemical Risk Information Platform
cm^3	Cubic Centimeter(s)
COC	Concentration of Concern
CPCat	Chemical and Product Categories
CSCL	Chemical Substances Control Law
CWA	Clean Water Act
DTSC	Department of Toxic Substances Control
EC	European Commission
ECHA	European Chemicals Agency
EG	Effluent Guideline
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
EU	European Union
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetic Act
g	Gram(s)
GBL	Gamma-Butyrolactone
HESIS	Hazard Evaluation System and Information Service
HHE	Health Hazard Evaluation
HPV	High Production Volume
IMAP	Inventory Multi-Tiered Assessment and Prioritisation
IRIS	Integrated Risk Information System
L	Liter(s)
lb	Pound
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
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
mg	Milligram(s)
µg	Microgram(s)

MMA	Monomethylamine
mmHg	Millimeter(s) of Mercury
mPa·s	Millipascal(s)-Second
MITI	Ministry of International Trade and Industry
MSDS	Material Safety Data Sheet
NAICS	North American Industry Classification System
NEI	National Emissions Inventory
NESHAP	National Emission Standards for Hazardous Air Pollutants
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NITE	National Institute of Technology and Evaluation
NMP	N-Methylpyrrolidone
NSPS	New Source Performance Standards
NTP	National Toxicology Program
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
OPP	Office of Pesticide Programs
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PDE	Permissible Daily Exposure
PEL	Permissible Exposure Limit
POD	Point of Departure
POTW	Publicly Owned Treatment Works
ppm	Part(s) per Million
QC	Quality Control
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SDWA	Safe Drinking Water Act
SNAP	Significant New Alternatives Policy
SOCMI	Synthetic Organic Chemical Manufacturing Industry
STORET	STOrage and RETrieval system for water quality monitoring data
SVHC	Substance of Very High Concern
TCCR	Transparent, Clear, Consistent, and Reasonable
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TWA	Time-Weighted Average
U.S.	United States
USGS	United States Geological Survey
UV	Ultraviolet
VOC	Volatile Organic Compound
WQP	Water Quality Portal
WWTP	Wastewater Treatment Plant

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 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. This document fulfills the TSCA § 6(b)(4)(D) requirement for n-methylpyrrolidone.

This document presents the scope of the risk evaluation to be conducted for n-methylpyrrolidone. If a hazard, exposure, condition of use or potentially exposed or susceptible subpopulation has not been discussed, EPA, at this point in time, is not intending to include it in the scope of the risk evaluation. As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, with respect to conditions of use in conducting a risk evaluation under TSCA, EPA will first identify "circumstances" that constitute "conditions of use" for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. Time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a problem formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluation for NMP. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

N-Methylpyrrolidone (NMP), also called n-methyl-2-pyrrolidone, or 1-methyl-2-pyrrolidone is a high production volume chemical that is often used as a substitute for chlorinated solvents due to its physical and chemical properties. NMP is subject to a number of federal and state regulations and reporting requirements. In the final 2015 risk assessment, EPA identified risks from NMP use in commercial and consumer paint removal based on aggregated inhalation, dermal and vapor-through-skin exposure routes. The Agency determined those risks were unreasonable and, on January 19, 2017, proposed restrictions under TSCA section 6 to address risks to consumers and most commercial users (82 FR 7464, January 19, 2017). Along with other reasonably available information, EPA will use the existing TSCA risk assessments to inform its development of the NMP risk evaluation.

The initial conceptual models presented in Section 2 identify the conditions of use; exposure pathways (e.g., media); exposure routes (e.g., inhalation, dermal, oral); potentially exposed populations, including potentially exposed or susceptible subpopulations; and hazards EPA expects to evaluate based on the inherent hazards of NMP. Dermal and inhalation pathways are expected to be the primary routes of exposure for all populations.

This document presents occupational scenarios in which workers and occupational non-users may be exposed to NMP during various conditions of use, such as polymer production, semiconductor fabrication and lithium ion battery manufacturing. It also presents a consumer model which depicts exposures that may result from consumer use of NMP containing products in indoor or outdoor environments. EPA believes that workers, consumers, bystanders, and certain other groups of individuals may experience greater exposures than the general population. EPA will evaluate whether other groups of individuals within the general population may be exposed via pathways that are distinct from the general population due to unique characteristics (e.g., life stage, behaviors, activities, duration) or have greater susceptibility than the general population, and determine whether they should therefore be considered as potentially exposed or susceptible subpopulations for the purposes of this risk evaluation.

General population exposures may occur as a result of industrial, commercial and consumer activities. NMP degrades readily and is therefore expected to exhibit low bioaccumulation potential and low persistence upon release into the environment. Most environmental releases reported in the 2015 Toxics Release Inventory were to land; however, NMP is mobile in soil and miscible in water. As such, NMP releases to air and land may ultimately migrate to ground water. EPA expects to consider these releases as they relate to occupational, consumer and general population exposures.

NMP has a robust toxicological database, with a number of hazards identified for human receptors including adverse effects on hepatic, renal, immune, reproductive/developmental and central nervous systems; however, reproductive/developmental effects generally represent the most sensitive health outcome. In the previous NMP risk evaluation completed in 2015, published reports of acute toxicity, irritation, systemic effects (e.g., body weight changes), neurotoxicity, and reproductive/developmental toxicity were compiled and reviewed. EPA also expects to consider the hazards of NMP exposure to ecological receptors, including aquatic and terrestrial organisms. These hazards will be evaluated based on the specific exposure scenarios identified. Along with other reasonably available information, EPA will use the existing TSCA risk assessments to inform its development of the NMP risk evaluation.

The initial analysis plan describes EPA's plan for conducting systematic review of readily available information and identification of assessment approaches to be used in conducting the risk evaluation for NMP. The initial analysis plan will be used to develop the problem formulation and final analysis plan for the NMP risk evaluation.

1 INTRODUCTION

This document presents the scope of the risk evaluation to be conducted for NMP. If a condition of use has not been discussed, EPA, at this point in time, is not intending to include that condition of use in the scope of the risk evaluation. Moreover, during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation. Any condition of use that will not be evaluated will be clearly described in the problem formulation document.

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act (TSCA), the nation's primary chemicals management law, was signed into law. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

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). 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. On February 14, 2017, EPA convened a public meeting to receive input and information to assist the Agency in its efforts to establish the scope of the risk evaluations under development for the ten chemical substances designated in December 2016 for risk evaluations pursuant to TSCA. EPA provided the public an opportunity to identify information, via oral comment or by submission to a public docket, specifically related to the conditions of use for the ten chemical substances. EPA used this information in developing this scope document, which fulfills the TSCA § 6(b)(4)(D) requirement for NMP.

As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, in conducting a risk evaluation under TSCA EPA will first identify "circumstances" that constitute "conditions of use" for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion. Based on legislative history, statutory structure and other evidence of Congressional intent, EPA has determined that certain activities may not generally be considered to be conditions of use. In exercising its discretion, for example, EPA would not generally consider that a single unsubstantiated or anecdotal statement (or even a few isolated statements) on the internet that a

chemical can be used for a particular purpose would necessitate concluding that this represented part of the chemical substance's "conditions of use." As a further example, although the definition could be read literally to include all intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in some circumstances, EPA does not generally intend to include such activities in either a chemical substance's prioritization or risk evaluation. In addition, EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses.

Furthermore, in exercising its discretion under section 6(b)(4)(D) to identify the conditions of use that EPA expects to consider in a risk evaluation, EPA believes it is important for the Agency to have the discretion to make reasonable, technically sound scoping decisions in light of the overall objective of determining whether chemical substances in commerce present an unreasonable risk. Consequently, 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 meriting an unreasonable risk consideration. For example, EPA intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping, in order to determine which risk evaluation the potential risks from the chemical substance should be addressed in. As an additional example, EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only "de minimis" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks.

The situations identified above are examples of the kinds of discretion that EPA will exercise in determining what activities constitute conditions of use, and what conditions of use are to be included in the scope of any given risk evaluation. See the preamble to *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)* for further discussion of these issues.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. The first 10 chemical substances were not subject to the prioritization process that will be used in the future in accordance with amendments to TSCA. EPA expects to collect and screen much of the relevant

information about chemical substances that will be subject to the risk evaluation process during and before prioritization. The volume of data and information about the first 10 chemicals that is available to EPA is extremely large and EPA is still in the process of reviewing it, since the Agency had limited ability to process the information gathered before issuing the scope documents for the first 10 chemicals. As a result of the statutory timeframes, EPA had limited time to process all of the information gathered during scoping for the first 10 chemicals within the time provided in the statute for publication of the scopes after initiation of the risk evaluation process. For these reasons, EPA's initial screenings and designations with regard to applicability of data (e.g., on-topic vs. off-topic information and data) may change as EPA progresses through the risk evaluation process. Likewise, the Conceptual Models and Analysis Plans provided in the first 10 chemical scopes are designated as "Initial" to indicate that EPA expects to further refine them during problem formulation.

The aforementioned time constraints and uncertainty associated with developing the risk evaluation process rule has resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be. In addition, there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents. For these reasons, EPA will publish and take public comment on a problem formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

1.1 Regulatory History

EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to NMP. EPA compiled information available from federal, state, international and other government sources, as cited in Appendix A. During risk evaluation, EPA will evaluate and consider the impact of these existing laws and regulations in the problem formulation step to determine what, if any further analysis might be necessary as part 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.

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—information useful to EPA in preparing this scope for risk evaluation. In addition to using this information, EPA intends to conduct a full review of the data collected (see *NMP (CASRN 872-50-4) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0743) using the literature search strategy (see *Strategy for Conducting Literature Searches for NMP: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0743) to ensure that EPA is considering information that has been made available since these assessments were conducted.

In the previous NMP risk assessment (U.S. EPA, 2015), EPA identified risks from NMP use in commercial and consumer paint and coating removal based on aggregated inhalation, dermal and vapor-through-skin exposures. The Agency determined those risks were unreasonable and, on January 19, 2017, proposed restrictions under TSCA section 6 to address risks to consumers and most commercial users (82 FR 7464, January 19, 2017). Along with other reasonably available information, EPA will use the existing TSCA risk assessments to inform its development of the NMP risk evaluation.

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 of N-Methylpyrrolidone: Paint Removal Use CASRN 872-50-4 (2015)
U.S. EPA, Office of Pesticide Programs (OPP)	Re-assessment of pesticide inert ingredient exemption under the Food Quality Protection Act (2006a)
Other U.S.-Based Organizations	
California Office of Environmental Health Hazard Assessment (OEHHA)	Proposition 65 Maximum Allowable Dose Level for Reproductive Toxicity (2003)
International	
National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Australian Government	Human Health Tier III assessment (2013)
Environment Canada, Health Canada	Draft screening assessment of risks to human and ecological receptors (2017)
European Commission (EC), Scientific Committee on Occupational Exposure Limits (OELs)	Evaluation of occupational exposure limits for NMP (EC, 2016)

1.3 Data and Information Collection

EPA/OPPT generally applies a process and workflow that includes: (1) data collection; (2) data evaluation; and (3) integration of the scientific data used in risk assessments developed under TSCA. Scientific analysis is often iterative in nature as new knowledge is obtained. Hence, EPA/OPPT expects that multiple refinements regarding data collection will occur during the process of risk evaluation.

Data Collection: Data Search

EPA/OPPT conducted chemical-specific searches for data and information on physical and chemical properties; environmental fate and transport; conditions of use information; environmental exposures, human exposures, including potentially exposed or susceptible subpopulations; ecological hazards; 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. Generally, the search was not limited by date and was conducted on a wide range of data sources, including but not limited to: peer-reviewed literature 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, such as EPA Integrated Risk Information System (IRIS) assessments and the National Toxicology Program's (NTP) *Report on Carcinogens,* 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. The *Strategy for Conducting Literature Searches for NMP: Supplemental File for the TSCA Scope Document* provides details about the data sources and search terms that were used in the initial 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*. 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 into the subsequent data extraction and data evaluation steps. Prior to full-text review, EPA/OPPT anticipates refinements to the search and 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 and chemical properties; environmental fate and transport; chemical use/conditions of use information; human and environmental exposures, including potentially exposed or susceptible subpopulations identified by virtue of greater exposure; human health hazard, including potentially exposed or susceptible subpopulations identified by virtue of greater susceptibility; and ecological hazard), but within each data set, there are two broad categories or data tags: (1) o*n-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* 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, cancer, 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* 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*. This document provides a comprehensive list (bibliography) of the data sources identified by the initial search and the initial categorization for *on-topic* and *off-topic* references. Because systematic review is an iterative process, EPA/OPPT expects that some references may move from the *on-topic* to the *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.

2 SCOPE OF THE EVALUATION

As required by TSCA, the scope of the risk evaluation identifies the conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations that the Administrator expects to consider. To communicate and visually convey the relationships between these components, EPA is including an initial life cycle diagram and initial conceptual models that describe the actual or potential relationships between NMP and human and ecological receptors. An initial analysis plan is included which identifies, to the extent feasible, the approaches and methods EPA may use to assess exposures, effects (hazards) and risks under the conditions of use identified for NMP. As noted previously, EPA intends to refine this analysis plan during the problem formulation phase of risk evaluation.

2.1 Physical and Chemical Properties

Physical and chemical properties influence the environmental behavior and the toxic properties of a chemical, thereby informing the potential conditions of use, exposure pathways and routes and related hazards that EPA intends to consider. For scope development, EPA considered the measured or estimated physical and chemical properties set forth in Table 2-1.

Table 2-1. Physical and Chemical Properties of NMP

Property	Value [a]	Reference
Molecular formula	C_5H_9ON	O'Neil et al. (2006)
Molecular weight	99.1 g/mole	O'Neil et al. (2006)
Physical form	Colorless to slightly 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	0.19 mmHg at 25°C	(EC, 2000)
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 (2012a)
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.

NMP is a polar solvent with low viscosity and low volatility that is miscible in water and organic solvents. It exhibits low flammability and is not readily oxidizable (Lide, 2001; O'Neil et al., 2001; EC, 2000); however, variations in humidity can produce a range of saturation concentrations in ambient air.

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

As the first step in preparing these scope documents, EPA identified, based on reasonably available information, the conditions of use for the subject chemicals. As further described in this document, EPA searched a number of 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 for risk evaluation 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 has been incorporated into this scope document to the extent appropriate, as indicated in Table 2.3. Thus, EPA believes the manufacture, processing, distribution, use and disposal activities identified in these documents constitute the intended, known, and reasonably foreseen activities associated with the subject chemicals, based on reasonably available information. The documents do not, in most cases, specify whether the activity under discussion is intended, known, or reasonably foreseen, in part due to the time constraints in preparing these documents.

2.2.2 Identification of Conditions of Use

As part of the scope, an initial life cycle diagram is provided (Figure 2-1) depicting the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, distribution, use (industrial, commercial, consumer; when distinguishable) and disposal. 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.

For the purposes of this scope, CDR use categories include the following: “industrial use” means use at a site at which one or more chemicals or mixtures are manufactured 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 or made available to consumers for their use (U.S. EPA, 2016c).

To understand conditions of use relative to one another and the associated exposure potential under those conditions of use, the initial life cycle diagram includes the production volume associated with each stage of the life cycle, as reported in the 2016 CDR reporting period (U.S. EPA, 2016c), when the production volume was not claimed as confidential business information (CBI). The 2016 CDR reporting data for NMP from EPA's Chemical Data Reporting (CDR) database are provided in Table 2-2 (U.S. EPA, 2016c).

Table 2-2. Production Volume of NMP in 2016 Chemical Data Reporting (CDR) 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, 2016c). 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.

Data reported for the 2016 CDR period (U.S. EPA, 2016c) indicate there are two manufacturers and 16 importers of NMP in the United States [1,2]. The number and identities of other companies that manufacture or import NMP are protected as CBI.

According to the 2016 CDR data, over 160 million pounds of NMP were produced or imported in the United States in 2015 (U.S. EPA, 2016c). NMP is widely used in the chemical manufacturing, petrochemical processing and electronics industries (FMI, 2015). In the commercial sector, it is primarily used for producing and removing paints, coatings and adhesives. Other commercial applications include use in solvents, reagents, sealers, inks and grouts. There is also growing demand for NMP use in semiconductor fabrication and lithium ion battery manufacturing.

EPA expects that some commercial products containing NMP may be available for purchase by consumers, such that many products are used in commercial and consumer applications. The initial life cycle diagram also shows the NMP production volume associated with each individual life cycle stage, where such information is reported in the 2016 CDR (U.S. EPA, 2016c).

Descriptions of the industrial, commercial and consumer use categories identified from the 2016 CDR and included in the life cycle diagram are summarized below. These descriptions provide a brief

[1] Manufacturers (including importers) are required to report under CDR if they meet certain production volume thresholds, generally 25,000 lbs or more of a chemical substance at any single site. Reporting is triggered if the annual reporting threshold is met during any of the calendar years since the last principal reporting year. In general, the reporting threshold remains 25,000 lbs per site; hHowever, a reduced reporting threshold (2,500 lbs) now applies to chemical substances subject to certain TSCA actions. https://www.epa.gov/chemical-data-reporting/how-report-under-chemical-data-reporting.

[2] Manufacture in the context of CDR means to manufacture, produce, or import for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances (40 CFR 711.3). https://www.epa.gov/sites/production/files/2015-12/documents/cdr_fact_sheet_importers_final_dec2015_0.pdf. Similarly, the term "manufacture" in the context of TRI means to produce, prepare, compound, or import an EPCRA Section 313 chemical. The term "manufacture" also includes coincidental production of an EPCRA Section 313 chemical (e.g., as a byproduct or impurity) as a result of the manufacture, processing, otherwise use or disposal of another chemical or mixture of chemicals. https://www.epa.gov/sites/production/files/documents/ry2012rfi.pdf.

overview of each use category; Appendix B contains more detailed descriptions (e.g., process descriptions, worker activities) for manufacturing, processing, distribution, use and disposal. 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; however, paint and coating removers containing NMP were evaluated in the previous risk assessment (U.S. EPA, 2015). 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.

In the previous assessment (U.S. EPA, 2015), EPA evaluated risks associated with NMP use in paint and coating removal. The Agency determined those risks were unreasonable and then on January 19, 2017, proposed restrictions under TSCA Section 6 to address risks to consumers and most commercial users

(82 FR 7464). While paint and coating removal falls under the conditions of use of NMP, the scenarios assessed in the 2015 risk assessment will not be re-evaluated in the risk evaluation to which this scope applies.

Figure 2-1 depicts the life cycle of NMP, from manufacturing to the point of disposal. The production volumes shown are from the 2016 CDR (U.S. EPA, 2016c). Activities related to distribution (e.g., loading, unloading) will be considered throughout the life cycle, rather than using a single distribution scenario. This initial life cycle diagram does not distinguish between industrial, commercial and consumer uses; however, EPA will further investigate and define the differences between these uses during risk evaluation.

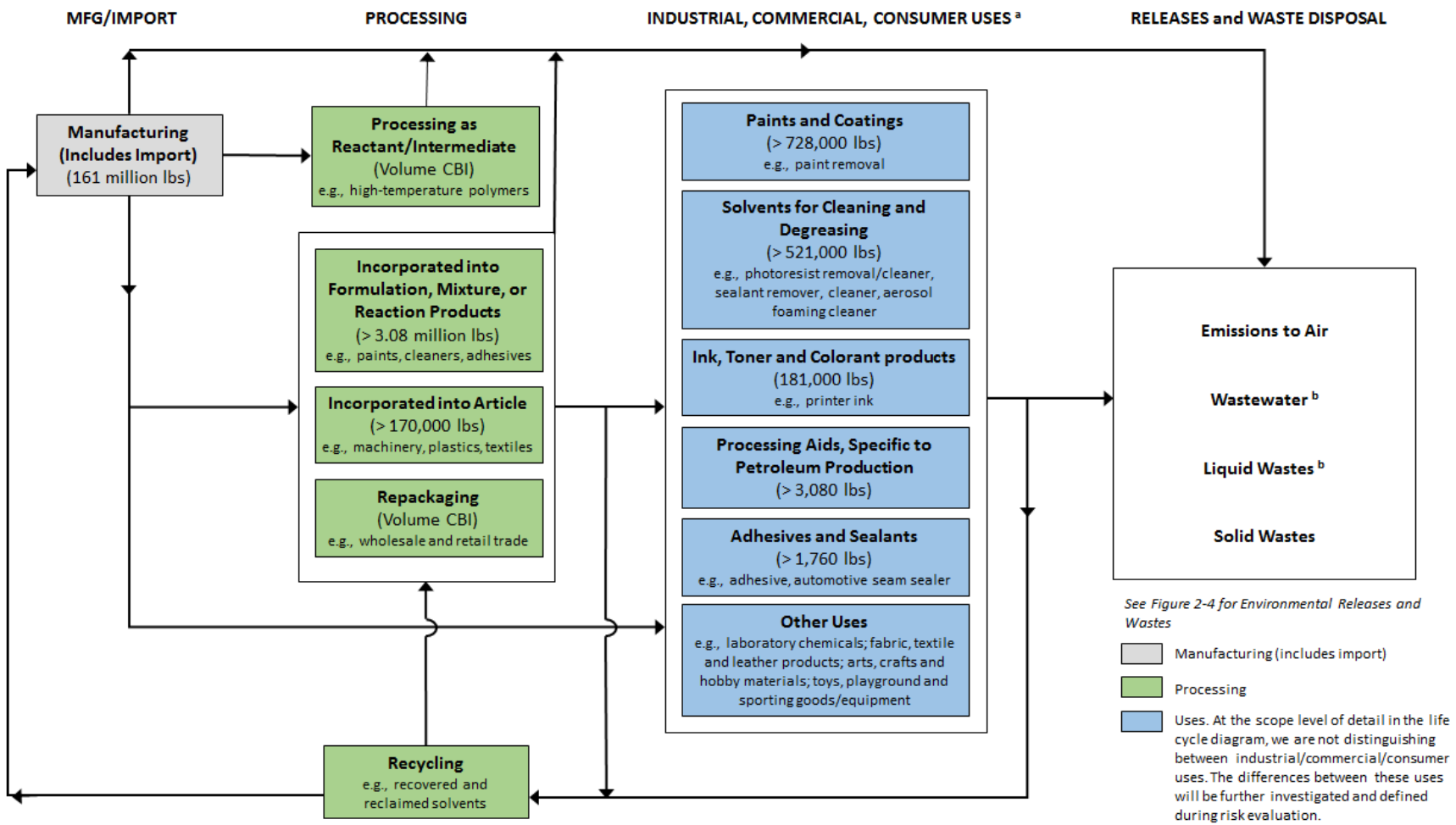

Figure 2-1. Initial NMP Life Cycle Diagram

The initial 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 (industrial, commercial, consumer) and disposal. The production volumes shown are from the 2016 CDR (2015 reporting year) (U.S. EPA, 2016c). 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.

[b] Wastewater: combination of water and organic liquid, where the organic content is less than 50%. Liquid Wastes: combination of water and organic liquid, where the organic content is greater than 50%.

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

Table 2-3. Categories and Subcategories of Conditions of Use for NMP

Life Cycle Stage	Category [a]	Subcategory [b]	Reference
Manufacture	Domestic Manufacture	Domestic Manufacture	U.S. EPA (2016c)
	Import	Import	U.S. EPA (2016c)
Processing	Processing as a reactant or intermediate	Intermediate in Plastic Material and Resin Manufacturing and in Pharmaceutical and Medicine Manufacturing	U.S. EPA (2016c), Public comments EPA-HQ-OPPT-2016-0743-0010, EPA-HQ-OPPT-2016-0743-0015, EPA-HQ-OPPT-2016-0743-0017
		Other	U.S. EPA (2016c)
	Incorporated into formulation, mixture or reaction product	Adhesives and sealant chemicals in Adhesive Manufacturing	U.S. EPA (2016c), 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 (2016c), 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 (2016c), 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 (2016c)

Life Cycle Stage	Category [a]	Subcategory [b]	Reference
Processing	Incorporated into formulation, mixture or reaction product	Processing aids, not otherwise listed in Plastic Material and Resin Manufacturing	U.S. EPA (2016c), 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
		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 (2016c), 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 (2016c), 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

Life Cycle Stage	Category [a]	Subcategory [b]	Reference
Processing	Incorporated into formulation, mixture or reaction product	Surface active agents in Soap, Cleaning Compound and Toilet Preparation Manufacturing	U.S. EPA (2016c), 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 (2016c), Market profile EPA-HQ-OPPT-2016-0743, Public comment EPA-HQ-OPPT-2016-0743-0016
	Incorporated into article	Lubricants and lubricant additives in Machinery Manufacturing	U.S. EPA (2016c), Market profile EPA-HQ-OPPT-2016-0743
		Paint additives and coating additives not described by other codes in Transportation Equipment Manufacturing	U.S. EPA (2016c)
		Solvents (which become part of product formulation or mixture), including in Textiles, Apparel and Leather Manufacturing	U.S. EPA (2016c), Market profile EPA-HQ-OPPT-2016-0743, Public comment EPA-HQ-OPPT-2016-0743-0027
		Other, including in Plastic Product Manufacturing	U.S. EPA (2016c), Market profile EPA-HQ-OPPT-2016-0743
	Repackaging	Wholesale and Retail Trade	U.S. EPA (2016c)
	Recycling	Recycling	U.S. EPA (2017b), U.S. EPA (2016c), 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 (2016c); Use document EPA-HQ-OPPT-2016-0743-0003

Life Cycle Stage	Category [a]	Subcategory [b]	Reference
Industrial commercial and consumer use	Paints and coatings	Paint and coating removers [c]	U.S. EPA (2016c), 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-2016-0743-0011, 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 (2016c), 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

Life Cycle Stage	Category [a]	Subcategory [b]	Reference
Industrial commercial and consumer use	Solvents (for cleaning or degreasing)	Use in Electrical Equipment, Appliance and Component Manufacturing.	U.S. EPA (2016c), 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 (2016c), Use document, EPA-HQ-OPPT-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 (2016c), Market profile EPA-HQ-OPPT-2016-0743, Public comment EPA-HQ-OPPT-2016-0743-0018
	Processing aids, specific to petroleum production	Petrochemical Manufacturing	U.S. EPA (2016c), Public comment, EPA-HQ-OPPT-2016-0743-0031
	Adhesives and sealants	Adhesives and sealant chemicals including binding agents	U.S. EPA (2016c), 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

Life Cycle Stage	Category [a]	Subcategory [b]	Reference
Industrial commercial and consumer use	Adhesives and sealants	Single component glues and adhesives, including lubricant adhesives	U.S. EPA (2016c), 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 (2016c), 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,
		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 (2016c)
		Automotive care products	U.S. EPA (2016c), Public comment, EPA-HQ-OPPT-2016-0743-0035
		Lubricants and greases	U.S. EPA (2016c)
		Metal products not covered elsewhere	U.S. EPA (2016c), 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 (2016c), Public comments EPA-HQ-OPPT-2016-0743-0007, EPA-HQ-OPPT-2016-0743-0009
		Lithium ion batteries	Market profile EPA-HQ-OPPT-2016-0743, Public comment EPA-HQ-OPPT-2016-0743-0005

Life Cycle Stage	Category [a]	Subcategory [b]	Reference
Industrial commercial and consumer use	Other uses	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
		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 (2016c), Public comment EPA-HQ-OPPT-2016-0743-0010, EPA-HQ-OPPT-2016-0743-0036
		Pharmaceutical and Medicine Manufacturing - functional fluids (closed systems)	U.S. EPA (2016c), 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	Wastewater or liquid wastes	Industrial pre-treatment or industrial wastewater treatment plant (WWTP)	U.S. EPA (2017b)
		Publicly owned treatment works (POTW)	U.S. EPA (2017b)
	Waste (solid or liquid)	Underground injection	U.S. EPA (2017b), Public comment EPA-HQ-OPPT-2016-0743-0031
		Landfill (municipal, hazardous or other land disposal)	
		Incinerators (municipal and hazardous waste)	
		Off-site waste transfer	U.S. EPA (2017b)
	Emissions to air	Emissions to air	U.S. EPA (2017b)

[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] This includes uses assessed in the previous EPA risk assessment (U.S. EPA, 2015) and therefore those uses are out of scope for the risk evaluation.

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 of the chemical and the exposure to receptors, including potentially exposed or susceptible subpopulations. EPA will take into account, where relevant, the duration, intensity (concentration), frequency and number 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 degradation or reaction of NMP with other species in the environment. Hence, knowledge of the environmental fate of NMP informs the determination of specific exposure pathways and potential human and environmental receptors EPA expects to consider in the risk evaluation. Table 2-4 provides environmental fate data that EPA has identified and considered in developing the scope for NMP.

Table 2-4. Environmental Fate Characteristics of NMP

Property or Endpoint	Value [a]	Reference
Direct photodegradation	Not available	
Indirect photodegradation	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 (1998)
	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 (2012a)
Soil organic carbon/water partition coefficient (log K_{oc})	0.9(estimated)	U.S. EPA (2012a)

[a] Measured unless otherwise noted.

NMP is expected to exist solely in the vapor phase upon atmospheric release based on its vapor pressure. NMP vapor is degraded via reaction with photochemically 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 by wet deposition, condensation or further reaction with hydroxyl radicals.

Although neat (pure) NMP is slightly volatile, the rate of 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 may migrate from soil to ground water (U.S. EPA, 2012a).

Measured bioconcentration studies for NMP were not presented in EPA's previous evaluation of risks associated with NMP use in paint removal (U.S. EPA, 2015); however, the estimated BAF and BCF values of 0.9 and 3.16, respectively, suggest that NMP does not bioaccumulate or bioconcentrate in aquatic organisms. Further, biodegradation studies have consistently shown this substance to be readily biodegradable (U.S. EPA, 2012a; OECD, 2007; U.S. EPA, 1999). Based on the available environmental fate data, NMP is expected to have low bioaccumulation potential and low persistence in the environment. The information provided in Table 2-2 was obtained from EPA's previous NMP risk assessment (U.S. EPA, 2015). A comprehensive literature search for environmental fate information has been conducted and the references identified will be reviewed and evaluated for potential inclusion or refinement in the risk evaluation.

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.

One source of information EPA expects to consider in evaluating exposure includes data reported under the Toxics Release Inventory (TRI) program. NMP has been a TRI-reportable substance under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313 rule since January 1, 1995.

Table 2-5 provides production-related waste management data for NMP reported by industrial facilities to the TRI program for 2015. Table 2-6 provides more detailed information on the quantity of NMP released to air, water or land.

Table 2-5. 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).					

Number of Facilities	Recycling	Energy Recovery	Treatment	Releases [a, b, c]	Total Production Related Waste
[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 release quantities disposed of by a receiving facility reporting to TRI.					

A total of 386 facilities submitted TRI reporting forms containing release and waste management data for NMP during the 2015 reporting cycle. According to 2015 TRI data (U.S. EPA, 2017b), approximately 14 thousand pounds of NMP were released to water, 1.4 million pounds were released to air and 6.4 million pounds were released to land (of which Class I underground injection is the primary disposal method).

Table 2-6. Summary of NMP TRI Releases to the Environment in 2015 (lbs)

	Number of Facilities	Air Releases		Water Releases	Land Releases			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]		
Subtotal		884,851	542,101		3,625,939	93,217	2,719,441		
Total	386	1,430,952		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) [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.									

While production-related waste managed shown in Table 2-5 excludes any quantities reported as catastrophic or one-time releases (TRI section 8 data), release quantities shown in Table 2-6 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 calculations for reported release range estimates (U.S. EPA, 2016b).

Other information sources may provide evidence of NMP releases, including EPA effluent guidelines promulgated under the Clean Water Act (CWA), National Emission Standards for Hazardous Air Pollutants (NESHAPs) promulgated under the Clean Air Act (CAA) or other EPA standards and regulations that set legal limits on the amount of NMP that can be emitted to a particular media. EPA expects to consider these data in conducting the exposure assessment of the risk evaluation for NMP.

2.3.3 Presence in the Environment and Biota

Monitoring studies or a collection of relevant and reliable monitoring data 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, 2012b). In addition, the Water Quality Portal (WQP), a cooperative service sponsored by the U.S. Geological Survey (USGS), EPA and the National Water Quality Monitoring Council (NWQMC, 2017) provides 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 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 regulation, 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 identified 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 air, water, sediment and soil. EPA expects to consider exposures to the environment and ecological receptors that occur via the exposure pathways or media shown in Figure 2-4 in conducting the risk evaluation for NMP.

2.3.5 Human Exposures

EPA expects to consider three broad categories of human exposures: occupational exposures, consumer exposures and general population exposures. Subpopulations within these exposure categories will also be considered as described herein.

2.3.5.1 Occupational Exposures

EPA expects to consider worker activities where there is a potential for NMP exposure under the various conditions of use described in Section 2.2. In addition, EPA expects to consider exposure to occupational non-users who do not directly handle the chemical but perform work in an area where it is present. When data and information are available to support the analysis, EPA also expects to consider the effect(s) that engineering controls and/or personal protective equipment have on occupational exposure levels.

In the previous risk evaluation of NMP use in paint removal (U.S. EPA, 2015), EPA assessed exposures to workers and occupational non-users from inhalation and dermal contact with the chemical. Risks associated with NMP use in paint removal will not be re-evaluated.

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.
- NMP use in process equipment (e.g., applying photoresists during silicon wafer production).
- Applying NMP-containing product formulations to substrates (e.g., adhesives and sealants)
- Cleaning and maintaining equipment.
- Sampling, repackaging or distributing product formulations containing NMP.
- Handling, transporting and/or disposing of wastes containing NMP.
- Performing other work activities in or near areas where NMP is used.

Based on these activities, EPA expects to consider inhalation exposure to NMP vapor/mist and dermal exposure (including skin contact with liquid and vapor forms of NMP). EPA also expects to consider the potential for worker exposure via the oral route, such as from incidental ingestion of mists that deposit in the upper respiratory tract and are swallowed.

The Occupational Safety and Health Administration (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-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.aiha.org/get-involved/AIHAGuidelineFoundation/WEELs/Documents/2011WEELValues.pdf.

Key data that inform occupational exposure assessment and which EPA expects to consider 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. The inspections can be random or targeted, or can be the result of a worker complaint. OSHA data can be obtained through the OSHA Integrated Management Information System (IMIS) at https://www.osha.gov/oshstats/index.html. Table Apx B-1 in Appendix B provides a summary of industry sectors with NMP personal monitoring 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/. During problem formulation, EPA will review these data and evaluate their utility in the risk evaluation.

2.3.5.2 Consumer Exposures

NMP can be found in consumer products and/or commercial products that are readily available for public purchase at common retailers [EPA-HQ-OPPT-2016-0743-0003 sections 3 and 4, (U.S. EPA, 2017a)] and can therefore result in exposures to consumers.

Exposure routes for consumers that use NMP-containing products (e.g., cleaning formulations, children's toys, textiles) may include inhalation of vapors/mists, dermal exposure to liquids and vapors and oral exposure through mists that deposit in the upper respiratory tract and are swallowed.

EPA expects to consider inhalation, dermal and oral exposures to consumers and bystanders resulting from consumer use of NMP-containing products in the home.

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. EPA expects to consider each exposure media, route and pathway to estimate general population exposures.

Inhalation

Based on the potential sources and pathways of exposure, EPA expects to consider inhalation exposures to the general population that may result from the NMP conditions of use.

Oral

Based on the potential sources and pathways of exposure, EPA expects to consider oral exposures to the general population that may result from the NMP conditions of use.

Dermal

Based on the potential sources and pathways of exposure, EPA expects to consider dermal exposures to the general population that may result from the conditions of use of NMP.

2.3.5.4 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 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.

Of the human receptors identified in the previous sections, EPA identifies the following as potentially exposed or susceptible subpopulations due to their *greater exposure* that EPA expects to consider in the risk evaluation (U.S. EPA, 2011):

- 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. Those who use NMP-containing products may 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 the conditions of use identified in Section 2.2 that result in environmental releases and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, distribution, use or disposal sites).

In developing exposure scenarios, EPA will evaluate readily available data to determine whether some human receptor groups may be exposed via exposure pathways that are distinct to a particular subpopulation or life stage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher 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 consider the following potentially exposed groups of human receptors: workers, occupational non-users, consumers, and bystanders associated with consumer use. As described above, EPA may 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*. Based on initial screening, EPA expects to consider the hazards of NMP identified in this scope 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 for acute exposure scenarios. This means that it is unlikely that every hazard identified in the scope will be considered for every exposure scenario.

2.4.1 Environmental Hazards

For scoping purposes, EPA consulted the following sources of environmental hazard data for NMP:

- 2006 re-evaluation of EPA's inert ingredient tolerance exemption for NMP under the Food Quality Protection Act (U.S. EPA, 2006a)
- 2015 Survey from the Danish Environmental Protection Agency (Danish EPA, 2015)
- 2015 TSCA Work Plan Chemical Risk Assessment for NMP Use in Paint Removal (U.S. EPA, 2015)
- 2017 Environment Canada and Health Canada Draft Screening Assessment for NMP (EC/HC, 2017)

In the previous evaluation of risks associated with NMP use in paint removal (U.S. EPA, 2015), EPA reviewed acute and chronic studies of NMP exposure to aquatic organisms, birds and mammals. EPA expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency (*NMP (CASRN 872-50-4) Bibliography: Supplemental File for the TSCA Scope Document*).

EPA expects to consider the hazards of NMP to aquatic organisms including fish and aquatic invertebrates exposed under acute and chronic exposure conditions.

EPA expects to consider the hazards of NMP to terrestrial organisms including aquatic plants, birds and mammals exposed under acute and chronic exposure conditions.

2.4.2 Human Health Hazards

The hazards of NMP exposure have been reviewed previously (U.S. EPA, 2015). A number of human health hazards have been identified for NMP including adverse effects on hepatic, renal, immune, reproductive/developmental and central nervous systems. In the previous NMP risk evaluation, published reports of acute toxicity, irritation, systemic effects (e.g., body weight changes), neurotoxicity, and reproductive/developmental toxicity were compiled and reviewed (U.S. EPA, 2015). EPA also expects to consider studies that have been published since this review, as identified in the literature search conducted by the Agency for NMP (*NMP (CASRN 872-50-4) Bibliography: Supplemental File for the TSCA Scope Document*), to ensure that information made available since the previous risk evaluation was conducted is taken into consideration. EPA expects to consider all potential hazards associated with NMP. Based on reasonably available information, the following are the hazards that have been identified in previous government documents and that EPA currently expects will likely be the focus of its analysis.

2.4.2.1 Non-Cancer Hazards

Acute Toxicity

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

Reproductive/Developmental Toxicity

EPA previously identified reproductive/developmental toxicity as a sensitive endpoint for evaluating risks associated with NMP exposure. Consistent with this past approach, EPA expects to consider reproductive/developmental toxicity as a relevant hazard benchmark for evaluating risks associated with acute and chronic exposures (see (U.S. EPA, 2015) for detailed discussion).

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 in the NMP risk evaluation. Consistent with the discussion in the preamble to the risk evaluation rule pertaining to conditions of use, EPA does not believe it makes sense to expend Agency resources evaluating hazards that EPA is confident are not presented by a chemical substance.

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 the risk evaluation for NMP, EPA expects to consider the following groups of human receptors: workers, occupational non-users, consumers, bystanders associated with consumer use and the

general population. In developing the hazard assessment, EPA will also evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

2.5 Initial Conceptual Models

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. As part of the scope for NMP, EPA developed three conceptual models, presented here.

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

Figure 2-2 presents an initial conceptual model which depicts the potential exposure pathways for human receptors from industrial and commercial activities and uses involving NMP. Workers and occupational non-users may be exposed to NMP via dermal and inhalation routes; however, inhalation exposures are expected to be limited for certain conditions of use due to the low volatility of NMP. In the previous risk evaluation of NMP use in paint removal (U.S. EPA, 2015), the dermal and inhalation routes were considered to be the most relevant exposure pathways; however, exposure to workers and occupational non-users may occur as a result of incidental ingestion of inhaled mists that deposit in the upper respiratory tract and are swallowed. EPA anticipates that populations living near industrial and commercial facilities that use NMP also may be exposed as a result of environmental releases.

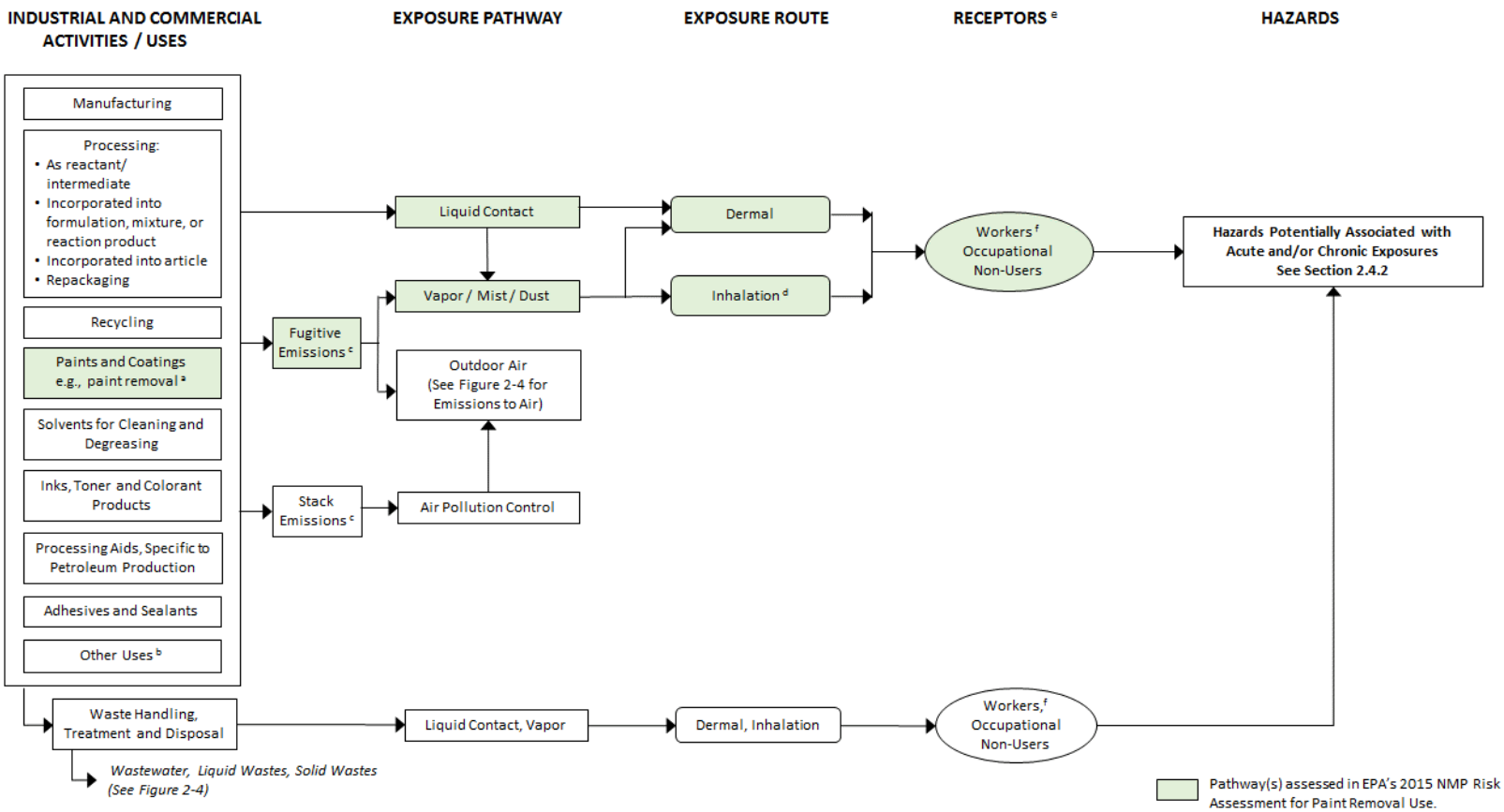

Figure 2-2. Initial NMP Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

The conceptual model presents 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 paint removal use; these uses are out of scope for the risk evaluation.

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

[c] Stack air emissions are emissions that occur through stacks, confined vents, ducts, pipes or other confined air streams. Fugitive air emissions are those that are not stack emissions and include 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] Includes exposure through mists that deposit in the upper respiratory tract and are swallowed.

[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 Initial Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

Figure 2-3 presents the initial conceptual model for human receptors from consumer uses of NMP. Similar to Figure 2-2, EPA expects that consumers and bystanders may be exposed via inhalation, dermal and oral routes. In the U.S. EPA (2015) risk assessment, dermal and inhalation exposures were assessed as the most likely exposure routes; however, oral exposure potential may exist for some conditions of use. It should be noted that some consumers may purchase and use products primarily intended for commercial use.

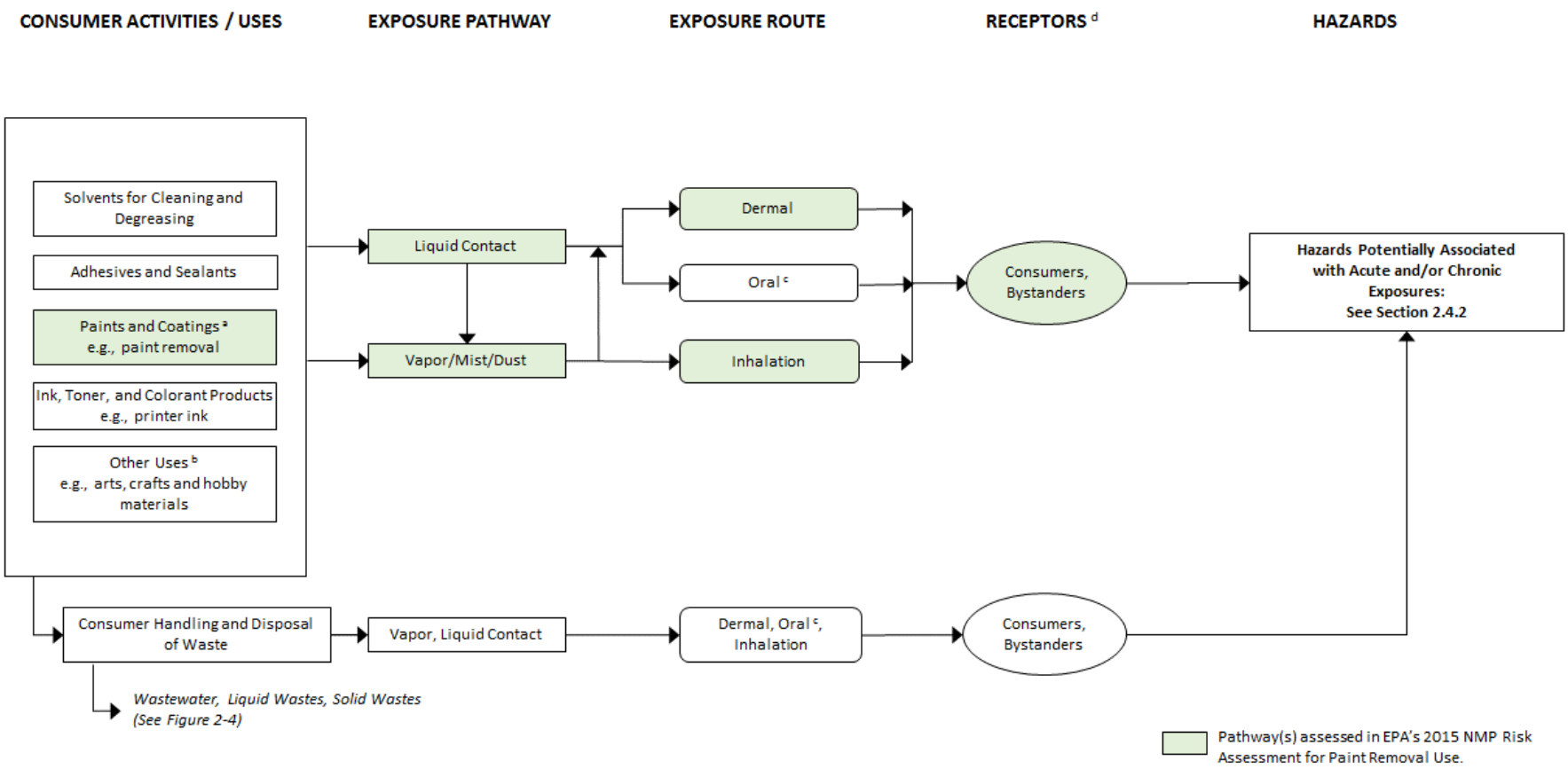

Figure 2-3. Initial NMP Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

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 paint removal use.

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

[c] Oral exposure may occur through incidental ingestion of NMP via dermal residues on skin or mists that deposit in the upper respiratory tract and are swallowed.

[d] Receptors include potentially exposed or susceptible subpopulations.

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

As shown in Figure 2-4, EPA anticipates that general populations living near industrial and commercial facilities using NMP may be exposed via inhalation of outdoor air. The general population also may be exposed to NMP via ingestion, inhalation or dermal contact with contaminated drinking water and/or improper disposal practices. In addition, aquatic and terrestrial life may be exposed via contaminated water, sediment and soil. Exposures to human and ecological receptors from NMP environmental releases are presented in Figure 2-4.

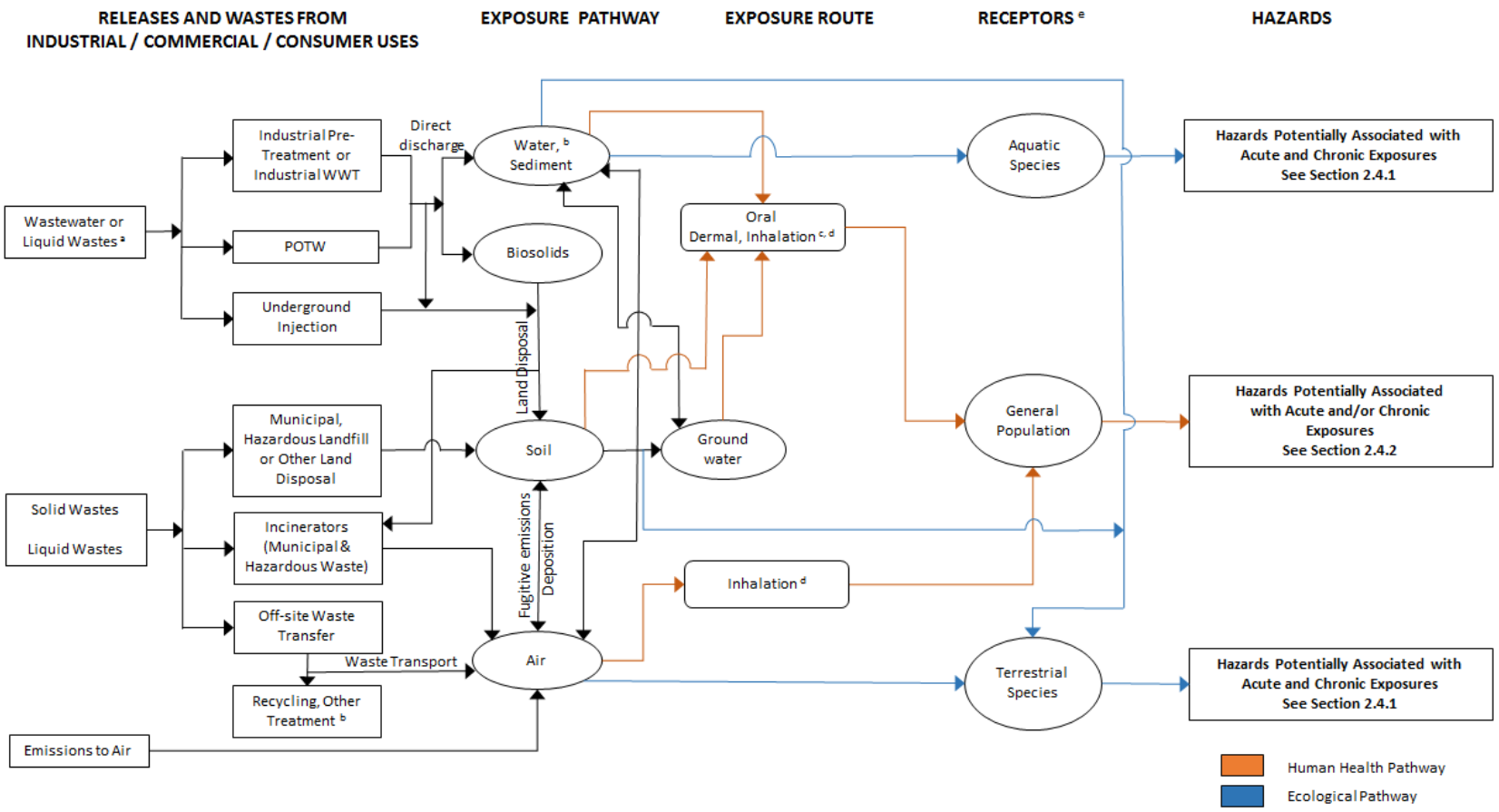

Figure 2-4. Initial NMP Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

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 Initial Analysis Plan

The initial analysis plan will be used to develop the eventual problem formulation and final analysis plan for the risk evaluation. While EPA has conducted a search for reasonably available data and information from public sources as described in Section 1.3, 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.

The analysis plan outlined here is based on the NMP conditions of use, as described in Section 2.2 of this scope. The analysis plan may be refined as EPA proceeds with its review of the information in the *NMP (CASRN 872-50-4) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0743. EPA will evaluate the weight of the scientific evidence for both hazard and exposure using a systematic review approach. As such, EPA will use explicit, pre-specified criteria and approaches to identify, select, assess, and summarize study findings. This approach will help to ensure that the review is complete, unbiased, reproducible, and transparent.

2.6.1 Exposure

2.6.1.1 Environmental Releases

EPA expects to consider and analyze releases to 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.
2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data collected under the TRI program).
3) Review measured or estimated release data for surrogate chemicals that have similar uses, volatility, and physical-chemical properties.
4) Understand and consider regulatory limits that may inform estimation of environmental releases.
5) Review and determine applicability of Organisation for Economic Co-operation and Development (OECD) Emission Scenario Documents and EPA Generic Scenarios to estimation of environmental releases.
6) Evaluate the weight of evidence for environmental release data.
7) Map or group condition(s) of use to a release assessment scenario(s).

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

2.6.1.3 Environmental Exposures

EPA expects to consider the following in developing its Environmental Exposure Assessment of NMP:

1) Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.
2) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data. Available exposure models will be evaluated and considered alongside available monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: release into the media of interest, fate and transport and characteristics of the environment.
3) Review reasonably available biomonitoring data. Consider whether these monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
4) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent data are available, and characterize exposed aquatic and terrestrial populations.
5) Evaluate the weight of evidence for environmental occurrence data and modeled estimates.
6) Map or group condition(s) of use to environmental assessment scenario(s).

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 (e.g., personal exposure monitoring data (direct measurements) and area monitoring data (indirect measurements)).
2) Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to 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.
4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.
5) Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios.
6) Evaluate the weight of the evidence of occupational exposure data.
7) Map or group each condition of use to occupational exposure assessment scenario(s).

2.6.1.5 Consumer Exposures

EPA expects to consider and analyze both consumers using a consumer product and bystanders associated with the consumer using the product as follows:

1) Review reasonably available consumer product-specific exposure data related to consumer uses/exposures (see Conceptual Model Figure 2-3).
2) Evaluate the weight of the evidence of consumer exposure data.
3) For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.

4) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further refined.
5) Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with those reported in monitoring data.
6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need to be further refined.
7) Map or group each condition of use to consumer exposure assessment scenario(s).

2.6.1.6 General Population

EPA expects to consider and analyze general population exposures as follows:

1) Review reasonably available environmental and biological monitoring data for media to which general population exposures are expected.
2) For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.
3) Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for consideration in a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
5) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.
6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need to be further defined.
7) Evaluate the weight of the evidence of general population exposure data.
8) Map or group each condition of use to general population exposure assessment scenario(s).

2.6.2 Hazards (Effects)

2.6.2.1 Environmental Hazards

EPA will conduct an Environmental Hazard Assessment of NMP as follows:

1) Review reasonably available environmental hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies).
2) Conduct hazard identification (the qualitative process of identifying acute and chronic endpoints) and concentration-response assessment (the quantitative relationship between hazard and exposure) for all identified environmental hazard endpoints.
3) Derive concentrations of concern (COC) for all identified ecological endpoints.
4) Evaluate the weight of the evidence of environmental hazard data.
5) Consider the route(s) of exposure, available biomonitoring data and available approaches to integrate exposure and hazard assessments.

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 (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology)
2) In evaluating available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.
3) Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for all identified human health hazard endpoints.
4) Derive points of departure (POD) where appropriate; conduct benchmark dose modeling depending on the available data. Adjust POD as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.
5) Evaluate the weight of evidence of human health hazard data.
6) Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.

2.6.3 Risk Characterization

Risk characterization is an integral component of the evaluation process for ecological and human health risks. EPA will drive the risk characterization in accordance with EPA's Risk Characterization Handbook (U.S. EPA, 2000). As defined in EPA's *Risk Characterization Policy*, "(U.S. EPA, 2000), 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 assessment being characterized. The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. In this regard, in evaluating whether information is reasonably available in the context of each risk evaluation, EPA will consider the added value of the information in characterizing the risk for which the information would be relevant. 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 (TCCR) 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 (TCCR) (U.S. EPA, 2000). EPA will also present information in this section consistent with approaches described in the Risk Evaluation Framework Rule.

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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	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
	presents a substantial risk of injury to health or the environment.	
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 01, 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	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
	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.	
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 (BSER) which (taking into account 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 (NAAQS) 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, C6-20 petroleum hydrocarbons, oxygenated organic solvents such as ketones, esters, alcohols, etc.)" for metals, electronics and precision cleaning and "Oxygenated

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		organic solvents (esters, ethers, alcohols, ketones)" for aerosol solvents (59 FR, March 18, 1994).
Safe Drinking Water Act (SDWA) – Section 1412 (b)	Requires EPA to publish a non-enforceable maximum contaminant level goals (MCLGs) for contaminants which 1. may have an adverse effect on the health of persons; 2. are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and 3. in the sole judgement of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems. When EPA publishes an MCLG, EPA must also promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either an enforceable maximum contaminant level (MCL), or a required treatment technique. Public water systems are required to comply with NPDWRs.	NMP was identified on both the Third (2009) and Fourth (2016) Contaminant Candidate Lists (74 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:

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		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 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, 5-261) 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

State Actions	Description of Action
	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 8-hr-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 of 3,200 µg/day and Maximum Allowable Dose Level (MADL) for dermal of 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 Methylene Chloride 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).
Australia	NMP was assessed under Human Health Tier III of the Inventory Multi-tiered Assessment and Prioritisation (IMAP) (National Industrial Chemicals

Country/Organization	Requirements and Restrictions
	Notification and Assessment Scheme, NICNAS, 2017, Human Health Tier III assessment for 2-Pyrrolidinone, 1-methyl-. 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).
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

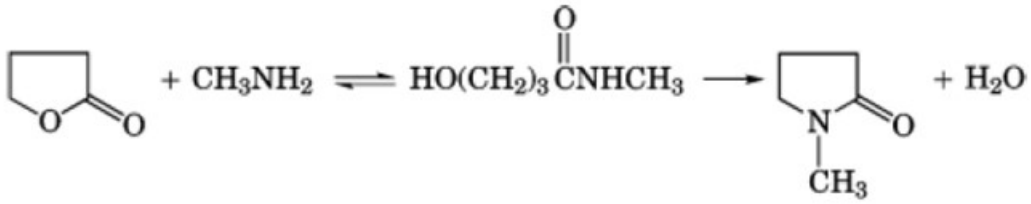
Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities for consideration.

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, 2016c).

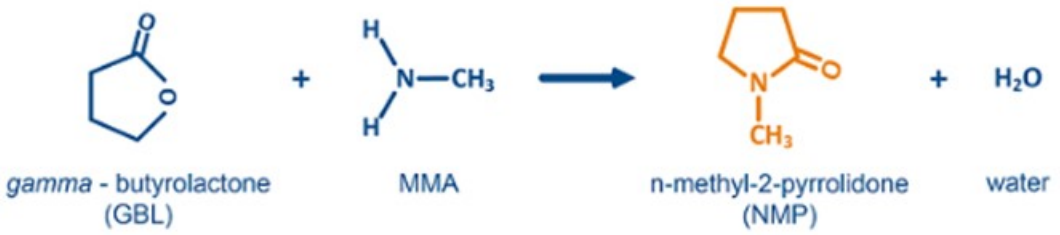
B.1.1.1 Domestic Manufacturing

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, 2005).

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 (QC) 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 HBCD and HBCD 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 and 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 (UV) 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 application, with techniques such as spray application, 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, 2016c).

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 certain 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, 2009). 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 summarizes the OSHA CEHD monitoring data by North American Industry Classification System (NAICS) code.

Table_Apx B-1. Summary of Industry Sectors with NMP Personal Air Monitoring Samples Obtained from OSHA Inspections Conducted Between 2011-2016

NAICS	NAICS Description
811420	Re-upholstery and furniture repair