Prepublication Copy Notice:

The Acting Director of the Office of Pollution Prevention and Toxics signed the following *Federal Register* document on November 14, 2016:

Title: **Alkylpyrrolidones; Significant New Use Rule**
ACTION: Proposed Rule
RIN: 2070-AK09
FRL: 9945-53
Docket No.: **EPA-HQ-OPPT-2015-0387**

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Once the official version of the document publishes in the *Federal Register*, the prepublication version of the document posted on the agency's internet will be replaced with a link to the document that appears in the *Federal Register* publication. At that time, you will also be able to access the on-line docket for this *Federal Register* document at *http://www.regulations.gov*.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the *Federal Register* document.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2015-0387; FRL-9945-53]

RIN 2070-AK09

Alkylpyrrolidones; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under the Toxic Substance Control Act (TSCA), EPA is proposing a significant new use rule (SNUR) for two alkylpyrrolidones: *N*-ethylpyrrolidone (NEP) and *N*-isopropylpyrrolidone (NiPP). The proposed significant new uses are any use of NiPP and any use of NEP except for the ongoing uses as a reactant, in silicone seal remover, coatings, consumer and commercial paint primer, and adhesives. Persons subject to the SNUR would be required to notify EPA at least 90 days before commencing any manufacturing or processing of the chemical substance for a significant new use. The required notification initiates EPA's evaluation of the conditions of use within the applicable review period. Manufacture and processing for the significant new use is unable to commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.

DATES: Comments must be received on or before [*insert date* 60 *days after date of*

publication in the **Federal Register**].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2015-0387, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Tyler Lloyd, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-4016; email address: *lloyd.tyler@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South

Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, or distribute in commerce chemical substances and mixtures. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Ship Building and Repairing (NAICS code 336611).
- Aircraft Manufacturing (NAICS code 336411).
- Museums (NAICS code 712110).
- Independent Artists, Writers, and Performers (NAICS code 711510).
- Reupholster and Furniture Repair (NAICS code 811420).
- Automotive Body Paint and Interior Repair Maintenance (NAICS code 811121).
- Flooring Contractors (NAICS code 238330).
- Painting and Wall Covering Contractors (NAICS code 238320).
- Adhesive Tape Manufacturing (NAICS code 339113)
- Adhesive Manufacturing (NAICS code 325520)

• Denture Adhesive Manufacturing (NAICS code 325620)

• Basic Chemical Manufacturing (NAICS code 325411)

• Pharmaceutical and Medicine Manufacturing (NAICS code 32541)

• Printing Ink Manufacturing (NAICS code 325910)

• Textile Leather Manufacturing (NAICS code 316998)

• Textile Manufacturing (NAICS code 325613)

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after [*insert date 30 days after the date of publication in the* **Federal Register**] are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

If you have any questions regarding the applicability of this action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2) (see Unit IV.). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(i)). TSCA furthermore prohibits such manufacturing or processing from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. What Action Is the Agency Taking?

EPA is proposing a SNUR for two alkylpyrrolidones: N-ethylpyrrolidone (NEP) and N-isopropylpyrrolidone (NiPP). The proposed significant new uses are any use of NiPP and any use of NEP except for the ongoing uses as a reactant, in silicone seal remover, coatings, consumer and commercial paint primer, and adhesives. The proposed significant new uses EPA has identified in this unit are uses that EPA believes are not

ongoing at the time of this proposed rule. EPA is requesting public comment on this proposal, and specifically on the Agency's understanding of ongoing uses for the chemicals identified. EPA would welcome specific documentation of any ongoing uses.

This proposed SNUR would require persons that intend to manufacture (including import) or process any of these chemicals for a significant new use, consistent with the requirements at 40 CFR 721.25, to notify EPA at least 90 days before commencing such manufacture or processing. This proposed SNUR would furthermore preclude the commencement of such manufacturing or processing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.

D. Why Is the Agency Taking this Action?

This proposed SNUR is necessary to ensure that EPA receives timely advance notice of any future manufacturing or processing of NEP and NiPP for new uses that may produce changes in human and environmental exposures, and to ensure that an appropriate determination (relevant to the risks of such manufacturing or processing) has been issued prior to the commencement of such manufacturing or processing. Today's action is furthermore necessary to ensure that, in the event that EPA determines: (1) that the significant new use presents an unreasonable risk under the conditions of use (without consideration of costs or other nonrisk factors, and including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA); (2) that the information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the significant new use; (3) that in the absence of sufficient information, the manufacture, processing, distribution in commerce, use, or

disposal of the substance, or any combination of such activities, may present an unreasonable risk (without consideration of costs or other nonrisk factors, and including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA), or (4) that there is sufficient potential for environmental release or human exposure (as defined in TSCA section 5(a)(3)(B)(ii)(II)), then manufacturing or processing for the significant new use cannot proceed until EPA has responded to the circumstances by taking the required actions under sections 5(e) or 5(f) of TSCA.

The two chemical substances subject to this proposed SNUR are structurally similar to and have similar physical-chemical properties to N-methylpyrrolidone (NMP), which EPA identified for risk evaluation as part of its Work Plan for Chemical Assessment under TSCA. Because of structural and physical-chemical similarity to NMP (Ref. 1, 2), these chemicals are expected to exhibit toxicity similar to NMP. The rationale and objectives for this proposed SNUR are explained in Unit III.

E. What are the Estimated Incremental Impacts of this Action?

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substances included in this proposed rule. This analysis (Ref. 3), which is available in the docket, is discussed in Unit IX., and is briefly summarized here.

In the event that a SNUN is submitted, costs are estimated to be less than $8,900 per SNUN submission for large business submitters and $6,500 for small business submitters. These estimates include the cost to prepare and submit the SNUN and the payment of a user fee. The proposed SNUR would require first-time submitters of any

TSCA section 5 notice to register their company and key users with the CDX reporting tool, deliver a CDX electronic signature to EPA, and establish and use a Pay.gov E-payment account before they may submit a SNUN, for a cost of approximately $200 per firm. However, these activities are only required of first time submitters of section 5 notices. In addition, for persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country, which is estimated to be approximately $80 per notification.

II. Chemical Substances Subject to this Proposed Rule

A. What Chemicals Are Included in the Proposed SNUR?

This proposed SNUR would apply to two alkylpyrrolidones: NiPP (Chemical Abstract Services Registry Number (CASRN) 3772-26-7) for any use, and to NEP (CASRN 2687-91-4) for any use except for the ongoing uses as a reactant, in silicone seal remover, coatings, consumer and commercial paint primer, and adhesives.

B. What Are the Production Volumes and Uses of NEP and NiPP?

In order to identify production volumes and uses of NEP and NiPP, EPA reviewed published literature including IHS' Chemical Economics Handbook, National Institute of Health's (NIH) Household Product Database, EPA's Chemical/Product Categorical Data (CPcat) database, the Consumer Product Information Database, the most recent data available from EPA's Chemical Data Reporting (CDR) program, general Google.com searches, Safety Data Sheets (SDSs), European Chemical Agency (ECHA) reports and risk assessments, the Danish Ministry of the Environment Surveys of Chemicals in Consumer Products, and other information from manufacturing company

websites (Ref. 3). NEP has a wide variety of potential applications as a chemical intermediate in cosmetics, paints and printing inks, paint strippers, pharmaceuticals, adhesives and cleaners for polymeric residue (Ref. 4), in adhesives and reprographic agents (Ref. 5), and as a replacement for NMP in coating and cleaning applications (Ref. 6). Many of these potential uses have not been identified by EPA to occur domestically. Four companies, including domestic manufacturers and importers, reported production of NEP between 1,000,000 to 10,000,000 million pounds to the 2012 CDR database (Ref. 7). The uses reported to CDR for NEP include industrial solvent and reactant uses in pharmaceuticals, paints and coatings, adhesives, textiles, and print ink manufacturing. EPA was able to identify several U.S. products containing NEP including silicone seal remover, coatings, consumer and commercial paint primer, and adhesives. Based on this available product data, EPA believes that the ongoing uses of NEP can be described as "use as a reactant, in silicone seal remover, coatings, consumer and commercial paint primer, and adhesives."

There are no known ongoing uses of NiPP as of November 17, 2016, the date of public release/web posting of this proposal.

C. What Are the Potential Health Effects of NEP and NiPP?

NEP is an organic solvent used as a substitute for NMP because of its similar solvent properties and very similar chemical structure (Ref. 1). NiPP is also a structurally similar analog with physical-chemical properties similar to NMP (Ref. 2). These two chemical substances, like NMP, are pyrrolidones with alkyl groups, but with two or three carbons in the carbon chain on the nitrogen, whereas NMP has a methyl group (one carbon) on the nitrogen. Because of their similar structure and physical-chemical

properties, NEP has been shown (Ref. 1) to, and NiPP is expected to, exhibit toxicity similar to NMP.

EPA has identified developmental effects as a key endpoint of concern from NMP exposure. Specifically, EPA has identified a number of biologically relevant, consistent, and sensitive developmental effects due to exposure to NMP through the oral and dermal routes, including decreased fetal and pup body weight, delayed ossification, skeletal malformations, and increased fetal and pup mortality (Ref. 8, 9, 10).

Study data are available on NEP and the developmental effects and malformations observed in the animal studies of NEP are similar to those observed in NMP studies (Ref. 1). For example, NEP exposure through oral and dermal routes is associated with adverse effects on fetal body weight, post-implantation loss (specifically late resorptions following oral exposures), and malformations. NEP exposure is also associated with skeletal malformations by oral route and cardiovascular malformation by oral and dermal routes in the animal studies (Ref. 1).

D. What Are the Potential Routes and Sources of Exposure to NEP and NiPP?

NMP is well absorbed following dermal exposures, such as during use of coating, paint stripping or cleaning products (Ref. 11, 12). Since NEP and NiPP are analogs of NMP, these chemical substances are expected to have similar routes of exposure. Dermal exposure and absorption, which includes dermal absorption from the vapor phase, typically contributes significantly to human exposure. Prolonged exposures to neat (i.e., pure) NMP increase the permeability of the skin. NMP is also absorbed via inhalation but the low vapor pressure and mild volatility can limit the amount of NMP available for

inhalation.

Given the similarity of their physical-chemical properties to those of NMP, NEP, and NiPP can be used in ways similar to NMP resulting in potential dermal and inhalation exposures.

III. Rationale and Objectives

A. Rationale

EPA is concerned about the potential for adverse health effects of NEP and NiPP based on data on the adverse health effects of NEP and because these chemicals are analogs of NMP that have similar physical-chemical properties and are therefore expected to or have been shown to have similar toxicological properties.

As discussed in Unit II, based on an extensive review of available information, EPA has determined that, at the time of publication of this proposed rule NiPP is not used for any use, and that NEP has ongoing uses as a reactant, in silicone seal remover, coatings, consumer and commercial paint primer, and adhesives (Ref. 3). EPA has concluded that action on these chemical substances is warranted and therefore any manufacturing or processing of NiPP for any use, and manufacture or processing of NEP for any use except for the ongoing uses as a reactant, in silicone seal remover, coatings, consumer and commercial paint primer, and adhesives, would be a significant new use.

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. If a person decides to begin manufacturing or processing any of these chemicals

for the use, the notice to EPA allows the Agency to evaluate the use according to the specific parameters and circumstances surrounding the conditions of use.

B. Objectives

Based on the considerations in Unit III.A., EPA wants to achieve the following objectives with regard to the significant new use(s) of NEP and NiPP that are designated in this proposed rule:

1. EPA would receive notice of any person's intent to manufacture or process the chemical substances for the described significant new use before that activity begins.

2. EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing the chemical substances for the described significant new use.

3. EPA would be able to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.

IV. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

1. The projected volume of manufacturing and processing of a chemical substance.

2. The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.

3. The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.

4. The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use of NEP or NiPP, as discussed in this unit, EPA considered relevant information about the toxicity or expected toxicity of these substances, likely human exposures and environmental releases associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA. EPA has preliminarily determined as significant new uses: any use of NiPP and any use of NEP except for the ongoing uses as a reactant, in silicone seal remover, coatings, consumer and commercial paint primer, and adhesives. Because NiPP is not used, and NEP is not currently used except as a reactant, in silicone seal remover, coatings, consumer and commercial paint primer, and adhesives, EPA believes any new use could increase the magnitude and duration of human exposure to these chemical substances. Exposure to NEP or NiPP may lead to adverse developmental health effects.

V. Applicability of General Provisions

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions

to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule.

Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's finding.

Persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import

certification appears at 40 CFR part 707, subpart B.

VI. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

EPA designates November 17, 2016 (the date of public release/web posting of this proposal) as the cutoff date for determining whether the new use is ongoing. This designation varies slightly from EPA's past practice of designating the date of **Federal Register** publication as the date for making this determination (Ref. 13). The objective of EPA's approach has been to ensure that a person could not defeat a SNUR by initiating a significant new use before the effective date of the final rule. In developing this proposal, EPA has recognized that, given EPA's practice of now posting proposed rules on its website a week or more in advance of **Federal Register** publication, this objective could be thwarted even before that publication. Thus, EPA has slightly modified its approach in this rulemaking and plans to follow this modified approach in future significant new use rulemakings. See the **Federal Register** of August 24, 2016, (81 FR 57846) (FRL-9951-06), (see page 57848).

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of November 17, 2016 would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until all TSCA prerequisites for the commencement of manufacture or processing have been satisfied. Consult the **Federal Register** document of April 24, 1990 (55 FR 17376) for a more detailed discussion of the cutoff date for ongoing uses.

VII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not usually require developing new information (e.g., generating test data) before submission of a SNUN. There is an exception: development of information is required where the chemical substance subject to the SNUR is also subject to a rule, order, or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)).

In the absence of a section 4 test rule covering the chemical substance, persons are required to submit only information in their possession or control and to describe any other information known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25, and 40 CFR 720.50). However, as a general matter, EPA recommends that SNUN submitters include information that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific information it believes may be useful in evaluating a significant new use.

Submitting a SNUN that does not itself include information sufficient to permit a reasoned evaluation may increase the likelihood that EPA will either respond with a determination that the information available to the Agency is insufficient to permit a reasoned evaluation of the health and environmental effects of the significant new use or, alternatively, that in the absence of sufficient information, the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance may present an unreasonable risk of injury.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs and define the terms of any potentially necessary controls if the submitter provides detailed information on human exposure and environmental releases that may result from the significant new uses of the chemical substance.

VIII. SNUN Submissions

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what information may be useful in evaluating a significant new use. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the substance. According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 721.25 and 40 CFR 720.40. E-PMN software is available electronically at *http://www.epa.gov/opptintr/newchems*.

IX. Economic Analysis

A. SNUNs

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substance included in this proposed rule (Ref. 3). In the event that a SNUN is submitted, costs are estimated at approximately $8,900 per SNUN submission for large business submitters

and $6,500 for small business submitters. These estimates include the cost to prepare and submit the SNUN, and the payment of a user fee. Businesses that submit a SNUN would be subject to either a $2,500 user fee required by 40 CFR 700.45(b)(2)(iii), or, if they are a small business with annual sales of less than $40 million when combined with those of the parent company (if any), a reduced user fee of $100 (40 CFR 700.45(b)(1)). EPA's complete economic analysis is available in the public docket for this proposed rule (Ref. 3).

B. Export Notification

Under section 12(b) of TSCA and the implementing regulations at 40 CFR part 707, subpart D, exporters must notify EPA if they export or intend to export a chemical substance or mixture for which, among other things, a rule has been proposed or promulgated under TSCA section 5. For persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical, depending on the number of required notifications (i.e., the number of countries to which the chemical is exported). While EPA is unable to make any estimate of the likely number of export notifications for the chemical covered in this proposed SNUR, as stated in the accompanying economic analysis of this proposed SNUR, the estimated cost of the export notification requirement on a per unit basis is $83.

X. Alternatives

Before proposing this SNUR, EPA considered the following alternative regulatory action: Promulgate a TSCA Section 8(a) Reporting Rule.

Under a TSCA section 8(a) rule, EPA could, among other things, generally require persons to report information to the Agency when they intend to manufacture or process a listed chemical for a specific use or any use. However, for NEP and NiPP, the use of TSCA section 8(a) rather than SNUR authority would have several limitations. First, if EPA were to require reporting under TSCA section 8(a) instead of TSCA section 5(a), that action would not ensure that EPA receives timely advance notice of any future manufacturing or processing of NEP and NiPP for new uses that may produce changes in human and environmental exposures. Nor would it ensure that an appropriate determination (relevant to the risks of such manufacturing or processing) has been issued prior to the commencement of such manufacturing or processing. Furthermore, a TSCA section 8(a) rule would not ensure that, in the event that EPA determines: (1) that the significant new use presents an unreasonable risk under the conditions of use (without consideration of costs or other nonrisk factors, and including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA); (2) that the information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the significant new use; (3) that in the absence of sufficient information, the manufacture, processing, distribution in commerce, use, or disposal of the substance, or any combination of such activities, may present an unreasonable risk (without consideration of costs or other nonrisk factors, and including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA), or (4) that there is sufficient potential for environmental release or human exposure (as defined in TSCA section 5(a)(3)(B)(ii)(II)), then manufacturing or processing for the significant new use cannot proceed until EPA has responded to the

circumstances by taking the required actions under sections 5(e) or 5(f) of TSCA.

In addition, EPA may not receive important information from small businesses, because such firms generally are exempt from TSCA section 8(a) reporting requirements (see TSCA sections 8(a)(1)(A) and 8(a)(1)(B)). In view of the level of health concerns about NEP and NiPP if used for a proposed significant new use, EPA believes that a TSCA section 8(a) rule for this substance would not meet EPA's regulatory objectives.

XI. Scientific Standards, Evidence, and Available Information

EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science, as applicable. These information sources supply information relevant to whether a particular use would be a significant new use, based on relevant factors including those listed under TSCA section 5(a)(2). As noted in Unit III, EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use.

The clarity and completeness of the data, assumptions, methods, quality assurance, and analyses employed in EPA's decision are documented, as applicable and to the extent necessary for purposes of this proposed significant new use rule, in Unit II and in the references noted above. EPA recognizes, based on the available information, that there is variability and uncertainty in whether any particular significant new use would actually present an unreasonable risk. For precisely this reason, it is appropriate to secure a future notice and review process for these uses, at such time as they are known more definitely. The extent to which the various information, procedures, measures,

methods, protocols, methodologies or models used in EPA's decision have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for a significant new use rule

XII. Request for Comment

A. Do you have comments or information about ongoing uses?

EPA welcomes comment on all aspects of this proposed rule. EPA based its understanding of the use profile of these chemicals on the published literature, the 2012 Chemical Data Reporting submissions, market research, and review of Safety Data Sheets. To confirm EPA's understanding, the Agency is requesting public comment on all aspects of this proposed rule, including EPA's understanding that NiPP is not currently used, and NEP is not used except as a reactant, in silicone seal remover, coatings, consumer and commercial paint primer, and adhesives. In providing comments on an ongoing use of NEP and NiPP, it would be helpful if you provide sufficient information for EPA to substantiate any assertions of use. EPA does not have specific information on the concentration by weight of NEP currently being used in silicone seal remover, coatings, consumer and commercial paint primer, and adhesives. If this information were available, EPA could better characterize the use. As such, EPA requests comment on the concentration by weight of NEP currently being used in silicone seal remover, coatings, consumer and commercial paint primer, and adhesives.

B. What Should I Consider as I Prepare my Comments for EPA?

1. *Submitting CBI*. It is EPA's policy to include all comments received in the public docket without change or further notice to the commenter and to make the

comments available on-line at *www.regulations.gov*, including any personal information provided, unless a comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM that you mail to EPA as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2, subpart B.

2. *Tips for preparing your comments*. When preparing and submitting your comments, see the commenting tips at *http://www2.epa.gov/dockets/commenting-epa-dockets#tips*.

XIII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. ECHA, Committee for Risk Assessment. Annex 1 Background document to the

Opinion proposing harmonised classification and labelling at Community level of *N*-ethyl-2-pyrrolidone (NEP). ECHA/RAC/CLH-O-0000002192-83-01/A1. 2011.

2. Vandeputte, Bart; Moonen, Kristof; and Roose, Peter. Use of improved *N*-alkyl pyrrolidone solvents. Google Patents. Publication Number: US20150057375 A1. Filing Date: January 17, 2013. Publication Date: February 26, 2015. Available at *http://www.google.com/patents/WO2013107822A1?cl=en*.

3. EPA. Economic Analysis of the Proposed Significant New Use Rule for Alkylpyrrolidones. March 31, 2016.

4. BASF. N-Ethylpyrrolidone-2 (NEP) Technical Data Sheet. July 2009. Available at *http://worldaccount.basf.com/wa/NAFTA~es_MX/Catalog/ChemicalsNAFTA/doc4/BASF/PRD/30036616/.pdf?urn=urn:documentum:eCommerce_sol_EU:09007bb280065a74.pdf*.

5. EPA. Chemical and Product Categories (CPCat) Database. Accessed September 2015. Available at *http://actor.epa.gov/cpcat/faces/home.xhtml*.

6. BASF Corp Germany. N-Ethylpyrrolidone. Accessed August 2016. Available at *https://www.standort-ludwigshafen.basf.de/group/corporate/site-ludwigshafen/en/brand/N_ETHYLPYRROLIDONE*.

7. EPA. Downloadable of the Non-Confidential Chemical Reporting Data (CDR) Database. Downloaded July 2014.

8. Sitarek, K., J. Stekiewicz, and W. Wasowicz. 2012. Evaluation of Reproductive

Disorders in Female Rats Exposed to N-Methyl-2-Pyrrolidone. Birth Defects Research (Part B), 95, 195-201.

9. Saillenfait, A. M., F. Gallissot, I. Langonne, and J. P. Sabate. 2002. Developmental Toxicity of NMethyl-2-Pyrrolidone Administered Orally to Rats. Food Chemistry and Toxicology, 40(11), 1705-1712.

10. Hass, U., S. P. Lund, and J. Elsner. 1994. Effects of Prenatal Exposure to N-Methylpyrrolidone on Postnatal Development and Behavior in Rats. Neurotoxicology and Teratology, 16(3), 241-249.

11. Bader, M., R. Wrbitzky, M. Blaszkewicz, M. Schaper, and C. van Thriel. 2008. Human Volunteer Study on the Inhalational and Dermal Absorption of N-Methyl-2-Pyrrolidone (NMP) from the Vapour Phase. Archives of Toxicology, 82(1), 13-20.

12. Keener, S., R. Wrbitzky, and M. Bader. 2007. Human Volunteer Study on the Influence of Exposure Dilution of Dermally Applied N-Methyl-2-Pyrrolidone (NMP) on the Urinary Elimination of NMP Metabolites. International Archives of Occupational and Environmental Health, 80(4), 327-334.

13. EPA. Significant New Uses of Certain Chemical Substances; Final Rule. RIVM, 2013). **Federal Register** (April 24, 1990, 55 FR 17376) (FRL-3658-5).

XIV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This proposed SNUR is not a “significant regulatory action” and was therefore

not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq*. Burden is defined in 5 CFR 1320.3(b). The information collection activities associated with existing chemical SNURs are already approved under OMB control number 2070-0038 (EPA ICR No. 1188); and the information collection activities associated with export notifications are already approved under OMB control number 2070-0030 (EPA ICR No. 0795). If an entity were to submit a SNUN to the Agency, the annual burden is estimated to be less than 100 hours per response, and the estimated burden for export notifications is less than 1.5 hours per notification. In both cases, burden is estimated to be reduced for submitters who have already registered to use the electronic submission system.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in Title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR, part 9, and included on the related collection instrument, or form, as applicable.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq*., I certify that

promulgation of this SNUR would not have a significant economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows.

A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a "significant new use." By definition of the word "new" and based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. Since this SNUR will require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact will occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of notices per year. During the six year period from 2005-2010, only three submitters self-identified as small in their SNUN submission (Ref. 3). EPA believes the cost of submitting a SNUN is relatively small compared to the cost of developing and marketing a chemical new to a firm or marketing a new use of the chemical and that the requirement to submit a SNUN generally does not have a significant economic impact.

Therefore, EPA believes that the potential economic impact of complying with this proposed SNUR is not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published as a final rule on August 8, 1997 (62 FR 42690) (FRL-5735-4), the Agency presented its general determination that proposed

and final SNURs are not expected to have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local, or Tribal government would be impacted by this rulemaking. As such, the requirements of sections 202, 203, 204, or 205 of UMRA, 2 U.S.C. 1531-1538, do not apply to this action.

E. Executive Order 13132: Federalism

This action will not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have any effect on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and

Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this action does not address environmental health or safety risks, and EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order.

H. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have any effect on energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve any technical standards, and is therefore not subject to considerations under section 12(d) of NTTAA, 15 U.S.C.272 note.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). This action does not affect the level of protection provided to human health or the environment.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: November 14, 2016.

Jeffery T. Morris,

Acting Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 721--[AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. Add §721.10925 to subpart E to read as follows**:**

§ 721.10925 Alkylpyrrolidones.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances *N*-ethylpyrrolidone (CASRN 2687-91-4) and *N*-isopropylpyrrolidone (CASRN 3772-26-7) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) For *N*-ethylpyrrolidone (CASRN 2687-91-4), any use except for use as reactant and in silicone seal remover, coatings, consumer and commercial paint primer, and adhesives.

(ii) For *N*-isopropylpyrrolidone (CASRN 3772-26-7), any use.

(b) [Reserved].