RJA 4/10/19
ALDS 04/11/19

[redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Significant New Use Notice Number:
	)	
	)	
	)	RECEIVED 04/09/19
	)	
	)	
[redacted]	)	S-18-13
	)	
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Consent Order and Determinations Supporting Consent Order

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PREAMBLE

I. INTRODUCTION

The attached Consent Order is entered into voluntarily by the Environmental Protection Agency ("EPA" or "the Agency") and [redacted] ("the Company"), regarding significant new use notice ("SNUN") S-18-0013 for the chemical substance lithium nickel oxide ("the SNUN substance"). The attached Consent Order is issued under § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)). The Company submitted the SNUN to EPA pursuant to § 5(a)(1)(B) of TSCA and 40 C.F.R. pt. 721.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of TSCA, any order issued under TSCA, or any consent order entered into under TSCA. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16 of TSCA, and to specific enforcement and seizure pursuant to § 17 of TSCA. In addition, chemical substances subject to an order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE CONSENT ORDER

The attached Consent Order requires the Company to:

(a) provide personal protective equipment to its workers to prevent dermal exposure;

(b) provide NIOSH-certified respirators with at least an APF of 50 to its workers to mitigate inhalation exposure;

(c) as an alternative to using respirators, maintain workplace airborne concentrations of the SNUN substance at or below a specified New Chemical Exposure Limit ("NCEL") of 0.05 mg/m^3,

verified by actual exposure monitoring data (to pursuc this option, a sampling and analytical method must be developed by the Company, verified by an independent third-party laboratory, and submitted to EPA);

(d) label containers of the SNUN substance and provide Safety Data Sheets ("SDSs") or Material Safety Data Sheets ("MSDSs") and worker training in accordance with the provisions of the Hazard Communication Program section;

(e) comply with the Release to Water provisions of the attached Consent Order; and,

(f) maintain certain records.

III. CONTENTS OF SNUN

By signing the attached Consent Order, the Company represents that it has carefully reviewed this document and agrees that all information herein that is claimed as confidential by the Company is correctly identified within brackets, that any information that is not bracketed is not claimed as confidential, and that the Company has previously submitted any information so marked to EPA under a claim of confidentiality in accordance with the requirements of TSCA and applicable regulations. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

Confidential Business Information Claims (Bracketed in the Preamble and the attached Consent Order):

Submitter Identity, Chemical Composition, Production Volume, Processing and Use Descriptions.

Chemical Identity:

Specific: Lithium nickel oxide

Generic: N/A

Use:

Specific: [redacted]

Generic: Chemical Intermediate

Maximum Estimated 12-Month Production Volume: [redacted]

Test Data Submitted with SNUN: none

IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

The following is EPA's assessment regarding the probable human and environmental toxicity, human exposure and environmental release of the SNUN substance, based on the information currently available to the Agency.

Human Health Effects Summary:

Absorption: Absorption is expected to be nil through the skin based on physical-chemical (pchem) properties and poor through the lungs and GI tract based on analogs.

Toxicological Endpoints of Concern: lung overload, neurotoxicity, kidney toxicity, developmental toxicity, thyroid toxicity, immunotoxicity, sensitization, mutagenicity and oncogenicity.

Basis: There is concern for lung overload based on poorly soluble particulates. There is concern for neurotoxicity, kidney toxicity, developmental toxicity, thyroid toxicity and immunotoxicity to the extent that lithium may be bioavailable. There is concern for sensitization, mutagenicity and oncogenicity to the extent that nickel may be bioavailable.

See https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemical-categories-used-review-new

Environmental Effects Summary:

Predictions are based on Structure Analysis Relationships (SAR) for mixed metal oxides. EPA estimated environmental hazard of this SNUN substance using hazard data on analogous chemicals. Based on hazard endpoints for an acceptable analog of the SNUN substance, EPA identified a high environmental hazard based on ecotoxicity data for green algae. The acute and chronic concentrations of concern (COCs) for the SNUN substance are 4 ppb and 1 ppb, respectively.

See https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemical-categories-used-review-new

Exposure and Environmental Release Summary:

	Manufacture	Use
# Sites	[redacted]	[redacted]
Workers (#/site)	[redacted]	[redacted]
Exposure (days/year)	[redacted]	[redacted]
Dermal Exposure (mg/day)	[redacted]	[redacted]
Inhalation Exposure (mg/day)	[redacted]	[redacted]

Risk to Workers:

Risks were identified for workers, for lung fibrosis and chronic inflammation via inhalation exposure based on quantitative hazard data for nickel oxide, a component of the SNUN substance (MOE = 22; benchmark MOE = 100). Risks were identified for workers, for sensitization, mutagenicity, and oncogenicity hazard endpoints via dermal and inhalation exposure based on nickel oxide. Risks for these hazard endpoints were not quantified due to a lack of suitable toxicity data for mutagenicity and oncogenicity and a lack of dose-response information for sensitization. Due to estimated exposures, these risks cannot be ruled out. However, worker exposures will be controlled by the use of dermal and respiratory PPE required by the consent order.

Risk to General Population:

General population risks via inhalation are not identified for lung fibrosis and chronic inflammation based on quantitative hazard data for a component of the SNUN, nickel oxide (MOE = 192, benchmark MOE = 100). Risks were not identified for general population for kidney toxicity, neurotoxicity, thyroid toxicity, and developmental effects via drinking water exposure based on quantitative hazard data for lithium a component of the SNUN substance (MOE greater than 800, benchmark MOE = 100). Although sensitization was identified as a possible hazard for the general population based on the presence of a chemical constituent in the SNUN (nickel oxide); general population risks are likely mitigated by dilution of the SNUN upon release into environmental media. There is insufficient information to assess general population risks for mutagenicity and carcinogenicity via dermal or inhalation exposure due to a lack of suitable toxicity on the SNUN or related analogues; therefore, EPA cannot make a quantitative risk

determination for these endpoints.

Risk to Consumers:

Risks to consumers were not assessed because consumer uses are not intended and exposures are not expected.

V. EPA'S DETERMINATION

Based on the foregoing:

(b) EPA is unable to determine whether the SNUN substance will present an unreasonable risk to health or the environment. Information available to EPA indicates that there is a potential for human or environmental exposure to the SNUN substance and that the SNUN substance may cause toxicity to aquatic organisms, lung overload, neurotoxicity, kidney toxicity, developmental toxicity, thyroid toxicity, immunotoxicity, sensitization, mutagenicity and oncogenicity based on intended and reasonably foreseen conditions of use. Therefore, pursuant to §§ 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, EPA determines that uncontrolled manufacture, processing, distribution in commerce, use, or disposal of the SNUN substance may present an unreasonable risk of injury to health or the environment and that the limitations imposed by the Consent Order are necessary to protect against such risk.

VI. INFORMATION REQUIRED OR POTENTIALLY USEFUL TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Potentially Useful Information. The attached Consent Order's restrictions on manufacture, processing, distribution in commerce, and use of the SNUN substance will remain in effect until

the attached Consent Order is modified or revoked by EPA based on submission of information described below or other relevant information to inform potential risks. Information may be required if a modification is requested to deviate from the conditions of the attached Consent Order. EPA encourages dialogue with Agency representatives to help determine how best the submitter can meet both the information needs and the objective of TSCA section 4(h).

The following types of information could be useful:

Information	Effects
Algae aquatic toxicity	Ecological
Pulmonary toxicity	Human Health

NOTE: Any potentially useful information described in the attached Consent Order was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the SNUN substance. Further, any such testing/information identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. Pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologics, or NAMs), if available, to generate the potentially useful information.

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Consent Order apply to all commercial manufacturing (including importing), processing, distribution in commerce, use and disposal of the chemical substance, lithium nickel oxide (S-18-0013) ("the SNUN substance") in the United States by [redacted] ("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the SNUN substance is exempt from the requirements of this Consent Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Consent Order.

(1) Export. Until the Company begins commercial manufacture of the SNUN substance for use in the United States, the requirements of this Consent Order do not apply to manufacture, processing or distribution in commerce of the SNUN substance solely for export in accordance with TSCA §§12(a) and 12(b), 40 C.F.R. § 720.3(s), 40 C.F.R. § 721.3and 40 C.F.R. Part 707. However, once the Company begins to manufacture, process, or distribute in commerce the SNUN substance for use in the United States, no further activity by the Company involving the SNUN

substance is exempt as "solely for export" even if some amount of the SNUN substance is later exported. At that point, the requirements of this Consent Order apply to all activities associated with the SNUN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the SNUN substance that are destined for export are subject to terms of the Consent Order.

(2) Research & Development ("R&D"). The requirements of this Consent Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the SNUN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 C.F.R. § 720.3(cc), and 40 C.F.R. § 721.45. The requirements of this Consent Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the SNUN substance when manufactured or processed under the conditions listed in t 40 C.F.R. § 720.47(a).

(c) Automatic Sunset. If the Company has obtained for the SNUN substance a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 C.F.R. § 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 C.F.R. § 723.50(c)(1) and (2) respectively, the Company must cease manufacture and processing under these exemptions as of the effective date of this Consent Order.

II. TERMS OF MANUFACTURE, DISTRIBUTION IN COMMERCE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

Except in accordance with the conditions described in this Consent Order, the Company is prohibited from manufacturing (which under TSCA includes importing), processing, distributing in commerce, using, or disposing of the SNUN substance in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the SNUN substance, and the completion of EPA's review of, and regulatory action based on, that information.

TESTING

(a) Section 8(c) Reporting. Reports of information on the SNUN substance which reasonably supports the conclusion that the SNUN substance presents a substantial risk of injury to health or the environment and which is required to be reported under § 8(e) of TSCA must reference the appropriate SNUN identification number for the SNUN substance and contain a statement that the SNUN substance is subject to this Consent Order. Additional information regarding § 8(e) reporting requirements can be found at *www.epa.gov/oppt/tsca8e*.

(b) Notice of Study Scheduling. The Company must notify, in writing, the EPA Monitoring Assistance and Media Programs Division, Office of Enforcement and Compliance Assurance (OECA), U.S. Environmental Protection Agency, of the following information within 10 days of scheduling any study required to be performed pursuant to this Consent Order, or within 15 days after the effective date of this Consent Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study;

(3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and,

(4) The appropriate SNUN identification number for each SNUN substance and a statement that the SNUN substance is subject to this Consent Order.

The written notice should be submitted to EPA/OECA as follows:

Postal Mail Address

U.S. Environmental Protection Agency

GLP Section Chief – Pesticides, Water and Toxics Branch

Monitoring Assistance and Media Programs Division (2227A)

Office of Enforcement and Compliance Assurance

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

Courier Delivery Address

U.S. Environmental Protection Agency

GLP Section Chief – Pesticides, Water and Toxics Branch

Monitoring Assistance and Media Programs Division (2227A)

Office of Enforcement and Compliance Assurance

Room 7117B

1200 Pennsylvania Avenue, N.W.

Washington, DC 20004

A copy of the letter submitted to EPA/OECA must also be submitted concurrently as a support document for the SNUN, using the procedures set out in 40 C.F.R. § 720.40 and § 721.25.

(c) Good Laboratory Practice Standards and Test Protocols. Each study performed to address the risks identified in this Consent Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 C.F.R. Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any study that will use a modified version of a published test guideline, the Company must submit written test protocols to EPA for review (submission of written test protocols is optional for tests that are to be conducted using unmodified published test guidelines). Protocols must be submitted as a support document for the SNUN, using the procedures set out in 40 C.F.R. § 720.40 and § 721.25. EPA will respond to the Company within 4 weeks of receiving the written protocols. EPA review of a test protocol does not mean pre-acceptance of test results.

(d) Unreasonable Risk.

EPA may notify the Company in writing that EPA finds that the data generated by a study (including studies not performed or information not generated under this Consent Order) are scientifically valid and unequivocal and indicate that, despite the terms of this Consent Order, the SNUN substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, processing, distribution, use and/or disposal of the SNUN substance to mitigate exposures to or to better characterize the risks presented by the SNUN substance.

Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, processing, distribution, use and disposal of the SNUN substance, unless either:

(1) within 2 weeks from receipt of the EPA notice, the Company complies with such requirements as the notice specifies; or

(2) within 4 weeks from receipt of the EPA notice, the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, process, distribute, use and dispose of the SNUN substance in accordance with the terms of this Consent Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company must comply with any requirements imposed by EPA's response or cease all manufacture, processing, distribution, use and disposal of the SNUN substance.

(e) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Section VI of this Consent Order.

PROTECTION IN THE WORKPLACE

(a) Establishment of Program. During manufacturing, processing, and use of the SNUN substance at any site controlled by the Company (including any associated packaging and storage and during

any cleaning or maintenance of equipment associated with the SNUN substance), the Company must establish a program pursuant to 40 C.F.R. § 721.63 whereby:

(1) General Dermal Protection. Engineering control measures (e.g. enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g. workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible to each person who is reasonably likely to be dermally exposed in the work area to the SNUN substance through direct handling of the SNUN substance or through contact with equipment on which the SNUN substance may exist, or because the SNUN substance becomes airborne in a form listed in subparagraph (a)(4) of this section. Where engineering, work practice, and administrative controls are not feasible or, if feasible, do not prevent exposure, each person subject to this exposure must be provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the SNUN substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with Occupational Safety and Health Administration ("OSHA") dermal protection requirements at 29 C.F.R. §§ 1910.132, 1910.133, and 1910.138.

(2) Demonstration of Imperviousness. The Company must demonstrate that each item of chemical protective clothing selected, including gloves, provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area. The Company may make this demonstration by any one or a combination of the following:

(i) Permeation Testing. Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely

combinations of chemical substances to which the clothing may be exposed in the work area. Permeation testing may be conducted according to the American Society for Testing and Materials ("ASTM") F739 "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact." Results must be reported as the cumulative permeation rate as a function of time, and must be documented in accordance with ASTM F739 using the format specified in ASTM F1194-99(2010) "Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials." Gloves may not be used for a time period longer than they are actually tested and must be replaced at the end of each work shift during which they are exposed to the SNUN substance.

(ii) Manufacturer's Specifications. Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the SNUN substance alone and in likely combination with other chemical substances in the work area.

(3) Respiratory Protection. Engineering control measures (e.g. enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g. workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, to each person who is reasonably likely to be exposed by inhalation in the work area to the SNUN substance in the form listed in subparagraph (a)(4) of this section. Where engineering, work practice, and administrative controls are not feasible or, if feasible, do not prevent exposure, each person subject to this exposure must be provided with and is required to wear, at a minimum, a National Institute for Occupational Safety and Health ("NIOSH")-certified respirator with an

Assigned Protection Factor ("APF") of 50, from the respirators listed in subparagraph (a)(5) of this section, and the respirator is used in accordance with OSHA and NIOSH respiratory protection requirements at 29 C.F.R. § 1910.134 and 42 C.F.R. Part 84. All respirators must be issued, used, and maintained according to an appropriate respiratory protection program under the OSHA requirements in 29 C.F.R. § 1910.134.

(4) Physical States. The following physical states of airborne chemical substances are listed for subparagraphs (a)(1) and (3) of this section:

(i) Particulate (including solids or liquid droplets),

(ii) Gas/vapor (all substances in the gas form), or

(iii) Combination Gas/Vapor and Particulate (gas and liquid/solid physical states are present; a good example is paint spray mist, which contains both liquid droplets and vapor).

(5) Authorized Respirators. The following NIOSH-certified respirators meet the minimum requirements for subparagraph (a)(3) of this section:

Assigned Protection Factor (APF)	Type of Respirator
50	(I) Any NIOSH-certified **air-purifying** full facepiece respirator equipped with N100 (if oil aerosols absent), R-100, or P-100 filter(s). (II) Any NIOSH-certified **powered air-purifying** respirator equipped with a tight-fitting facepiece (full facepiece) and equipped with HEPA filters. (III) Any NIOSH-certified negative pressure (demand) **supplied-air** respirator equipped with a full facepiece. (IV) Any NIOSH-certified continuous flow **supplied-air** respirator equipped with a tight-fitting facepiece (full facepiece). (V) Any NIOSH-certified negative pressure (demand) **self-contained breathing apparatus** (SCBA) equipped with a hood or helmet or a full facepiece.

(b) *De Minimis* Concentrations. The requirements of this section do not apply to quantities of the SNUN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the SNUN substance is identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Consent Order). This exemption is not available if the Company has reason to believe that, during intended activities, the SNUN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies. If this Consent Order contains New Chemical Exposure Limits provisions or Release to Water provisions that, respectively, specify a NCEL concentration ("TWA") or in-stream concentration ("N") less than the *de minimis* concentration specified here, then this *de minimis* exemption does not apply.

NEW CHEMICAL EXPOSURE LIMIT

(a) Alternative to Requirements of Respirator Section.

(1) EPA recommends and encourages the use of pollution prevention, source reduction, engineering controls and work practices, rather than respirators, as a means of controlling inhalation exposures whenever practicable.

(2) Whenever a person is reasonably likely to be exposed to the SNUN substances by inhalation, as an alternative to compliance with the respirator requirements in the Protection in the Workplace section of this Order, the Company may comply with the requirements of this New Chemical Exposure Limit section. However, before the Company may deviate from the respirator requirements in the Protection in the Workplace section of this Order, the Company must:

(i) submit to EPA a copy of the Company's sampling and analytical method for the SNUN substance, verified in accordance with subsection (c)(3) of this New Chemical Exposure Limit section;

(ii) obtain exposure monitoring results in accordance with this New Chemical Exposure Limit section; and,

(iii) based on those exposure monitoring results, select, provide, and ensure use if necessary of the appropriate respiratory protection specified in paragraph (e)(2) of this New Chemical Exposure Limit section by persons who are reasonably likely to be exposed to the SNUN substance by inhalation.

(3) After appropriate respiratory protection has been selected at a workplace based on the results of actual exposure monitoring conducted in accordance with this New Chemical Exposure Limit section, the Company must not, at that workplace, use the respiratory protection required in the Protection in the Workplace section of this Order unless it is the same as required by this New Chemical Exposure Limit section.

(b) Exposure Limit.

(1) General. The following new chemical exposure limit ("NCEL") for the SNUN substance is an interim level determined by EPA based on the limited information available to the Agency at the time of development of this Order. The NCEL for the SNUN substance is as follows:

(i) Time-Weighted Average ("TWA") Limit. The Company must ensure that no person is exposed to an airborne concentration of the SNUN substance in excess of 0.05 mg/m^3

(the NCEL) as an 8-hour time-weighted average, without using a respirator in accordance with subsection (e) of this New Chemical Exposure Limit section.

(ii) Non-8-Hour Work-shifts. For non-8-hour work-shifts, the NCEL for that work-shift (NCELn) must be determined by the following equation: NCELn = NCEL x (8/n) x [(24-n)/16], where n = the number of hours in the actual work-shift.

(2) Automatic Sunset. If, subsequent to the effective date of this Order, OSHA promulgates, pursuant to §6 of the Occupational Safety and Health Act, 29 U.S.C. 655, a final chemical-specific permissible exposure limit ("PEL") specifically applicable to this SNUN substance and the OSHA PEL is not challenged in court within 60 days of its promulgation, then any respirator requirements in the Protection in the Workplace section of this Order and any requirements of this New Chemical Exposure Limit section applicable to workers and situations subject to the OSHA PEL will automatically become null and void. However, the requirements of this Consent Order are not negated by any pre-existing OSHA PEL applicable to the SNUN substance.

(c) Performance-Criteria for Sampling and Analytical Method.

(1) Applicability. For initial development and validation of the sampling and analytical method for the SNUN substance, all the requirements of this subsection (c) apply. For subsequent exposure monitoring conducted pursuant to subsection (d) of this New Chemical Exposure Limit section, only the following requirements apply: (c)(4)(i), (4)(ii), (4)(iv)(II), (4)(v)(II), (8), and (9). Any deviation from the requirements of this subsection (c) must be approved in writing by EPA.

(2) Submission of Verified Method and Certification Statement. The Company must submit to EPA a copy of a validated sampling and analytical method for the SNUN substance

which satisfies the criteria specified in this subsection (c). The method description must expressly state how the method compares with each quantitative requirement specified in this subsection (c). The submission must include a written statement, signed by authorized officials of both the Company and the Laboratory, certifying the truth and accuracy of the independent laboratory verification conducted pursuant to subsection (c)(3). To assist EPA in identifying the document, it must state in a conspicuous, underlined subject-line at the top of the first page: "NCEL Sampling and Analytical Method for SNUN #_S-18-0013," after which the correct SNUN number for this chemical substance must be stated.

(3) Verification of Analytical Method by Independent Third-Party Laboratory.

(i) Verification. The Company must have an independent reference laboratory ("Laboratory") verify the validity of the analytical method for the SNUN substance, in accordance with the other requirements in this subsection (c)(3). It is the Company's responsibility to ensure that the Laboratory complies with all the requirements specified in this subsection (c)(3).

(ii) Independent Reference Laboratory. The independent reference laboratory must be a separate and distinct person (as defined at 40 CFR 720.3(x)) from the Company and from any other person who may have developed the method for the Company.

(iii) Accreditation. The Laboratory must be accredited by a formally recognized government or private laboratory accreditation program for chemical testing and/or analysis.

(iv) Good Laboratory Practice Standards. The Laboratory verification of the analytical method for the SNUN substance must comply with TSCA Good Laboratory Practice Standards ("GLPS") at 40 CFR Part 792. (Certain provisions of the TSCA GLPS applicable to toxicity testing in laboratory animals, such as 40 CFR 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are

clearly inapplicable to the NCEL requirements.) However, compliance with TSCA GLPS is not required under this New Chemical Exposure Limit section where the analytical method is verified by a laboratory accredited by either: (A) the American Industrial Hygiene Association ("AIHA") Industrial Hygiene Laboratory Accreditation Program ("IHLAP"); or (B) another comparable program approved in advance in writing by EPA.

(v) Analysis of Duplicate Samples. The Company must collect six duplicate samples (a total of 12) at the TWA concentration. The samples must be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the SNUN substance onto a sample collection device. The duplicate samples must be collected on identical collection media, at the same time, and under the same conditions. One set of six samples must immediately be analyzed by the Company, the other set of six samples must be analyzed by the Laboratory using the method developed by or for the Company.

(vi) Sample Storage Study. If the results of the analysis of duplicate samples pursuant to paragraph (c)(3)(v) do not satisfy the requirements in paragraph (c)(3)(vii), the Company must perform a sample storage study as follows:

(I) Triplicate Samples. The Company must collect six triplicate samples (a total of 18) at the TWA concentration. The samples must be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the SNUN substance onto a sample collection device. The triplicate samples must be collected on identical collection media, at the same time, and under the same conditions. One set of six samples must immediately be analyzed by the Company.

(II) Analysis After Sample Storage. A sample storage evaluation must be performed with the two remaining sets of six samples. One set of six samples must be analyzed by the Laboratory using the method developed by or for the Company, and the other must be analyzed by the Company on the same day as the Laboratory analyzes its six samples. Specialized storage conditions for the samples including extraction conditions, time from sampling to extraction, time from collection or extraction (if applicable) to analysis and storage conditions must be specified in the method description.

(vii) Comparison of Results. The difference between the results of the two sets of six samples analyzed by the Laboratory and the Company as required in either paragraph (c)(3)(v) or (c)(3)(vi)(II) must be evaluated using a two-sample t-test with unequal variances, and the two sides of the critical regions must not exceed a 5% significance level. (See Attachment C - Statistical Analysis of NCELs Analytical Method Verification Results.) The average of each set of six samples must be within 10% of the true value. If the average of each set of six samples is not within 10% of the true value, then the sample storage time between collection and analysis must be reduced until the average of each set of six samples is within 10% of the true value.

(4) Accuracy. The sampling and analytical method must clearly demonstrate the following:

(i) General. The sampling and analytical method, and all exposure monitoring data relied on by the Company, must be accurate to within ±25% at a 95% confidence level for concentrations of the SNUN substance ranging from one half the NCEL to twice the NCEL.

(ii) NCEL Quantitation Limits. The analytical method should be capable of reliably quantifying the SNUN substance across the full range of reasonably likely exposures. At a minimum, the analytical method must be capable of reliably quantifying from a lower quantitation

limit ("LQL") of one half the NCEL to an upper quantitation limit ("UQL") of at least twice the NCEL. If the Company obtains an exposure monitoring sample that is more than 10% above the actual UQL of the analytical method, the Company must comply with paragraph (e)(4)(i).

(iii) Lower Quantitation Limit Signal-To-Noise Ratio. The analytical method must be capable of quantifying the SNUN to a concentration of one half the NCEL with a signal that is at least five times the baseline noise level. Bascline noise must be amplified to a measurable level when possible, even if the required amplification is beyond that used in routine analysis of samples. (If baseline noise cannot be obtained, another reference must be selected. This may be a peak considered to be noise caused by the reagent matrix.) The sampling preparation method must be specified and the detection limit for the analytical procedure must be reported as mass per injection for chromatographic techniques.

(iv) Instrument Calibration.

(I) Initial Calibration. For method development and validation (but not subsequent exposure monitoring), the initial calibration must at a minimum consist of five (5) calibration standards with a linear correlation of 0.95 -- these five (5) calibration standards must consist of one standard at each of the following concentrations: one half the NCEL (0.5 x NCEL); between one half and one times the NCEL (>0.5 x NCEL,< 1 x NCEL); one times the NCEL (1 x NCEL); between one and two times the NCEL (>1 x NCEL, < 2 x NCEL), and twice the NCEL (2 x NCEL).

(II) Continuing Calibration. During each week of both method development/validation and subsequent exposure monitoring, the Company must conduct both an initial instrument calibration and a continuing calibration. The Company must perform at least one continuing calibration sample at the NCEL concentration, and at least one additional calibration

sample per every 10 samples analyzed. The continuing calibration sample must fall within ± 25% of the initial calibration value. If not, then the initial calibration must be repeated, and any samples associated with that outlying calibration check must be re-analyzed.

(v) Calculated Percent Recovery.

(I) Initial Calculation. For method development and validation, the Company must calculate the percent of the SNUN substance recovered by the analytical method from a sample containing a known quantity of the SNUN substance. The sample must be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the SNUN substance onto a sample collection device. (Such a sample is referred to as a "matrix spike"). The calculated percent recovery for each matrix spike must be greater than or equal to 75% and less than or equal to 125%. Spike concentrations for the SNUN substance must be included in the sampling and analytical method submitted to EPA.

(II) Subsequent Calculation. During each subsequent exposure monitoring episode or campaign, at least 1 matrix spike, prepared by injecting the SNUN substance onto a sample collection device, must be analyzed. (This matrix spike must be prepared at the NCEL concentration.)

(vi) Sampling Device Capacity. The capacity of the sampling device must be tested and results reported to show under a known and well-defined set of conditions that the device is capable of collecting the new chemical in solid, liquid or vapor phase with minimal loss. The sampling device's capacity (air volume and collected analyte mass) must be specified. For methods that use adsorbent tubes as the collection medium, evidence of the capacity must be provided in the form of breakthrough testing. This testing must be done at a concentration twice

the NCEL and under conditions similar to those expected in the workplace. Breakthrough is defined to have occurred when the concentration of the SNUN substance in the effluent stream is equal to 5% of the concentration of the influent stream, or when 20% of the SNUN substance is detected in the backup section of the sampler.

(vii) Sampling Device Desorption Efficiency. Where applicable, the desorption efficiency must be evaluated for the air sampling device. A minimum of six air samples spiked with the SNUN substance at least the NCEL concentration must be prepared. A recovery of at least 75% must be obtained for each of the six samples.

(5) Precision. The estimate of the coefficient of variation of each set of six samples from the controlled atmosphere test (spiked at 1.0 NCEL, per paragraphs (c)(3)(v) or (vi)) must be less than 0.105, including allowance of 0.05 for error due to sampling.

(6) Interpretation of Accuracy and Precision Data.

(i) If a single matrix spike recovery is less than 75% recovery or greater than 125% or the estimated precision is greater than 0.105, then the Company must re-prepare the matrix spike, re-sample, and re-analyze all samples associated with such matrix spike or triplicate samples.

(ii) For percent recoveries less than 90% but greater than 75%, correction for low recovery is required. Correct for recovery first by dividing the observed amount by the proportion recovered before determining if measurements fall below the NCEL. For example, if the observed level is 30 mg/m^3 and the percent recovery is 75%, use the value 30 $mg/m^3/(0.75) = 40$ mg/m^3 when determining whether the levels are below the exposure limit.

(7) Representativeness. All sample conditions used to develop the methodology must mimic the actual workplace environment expected to be monitored. Conditions such as the

temperature, humidity, lighting, and presence of other chemicals, etc. must mimic the conditions in the workplace to be monitored.

(8) Changes Affecting Validity. If the workplace environment changes from the initial conditions described in the verified sampling and analytical method in a way reasonably likely to invalidate the accuracy of the method, then the Company must comply with the respirator requirements in the Protection in the Workplace section of this Order, unless the Company re-validates the method to confirm that the requirements for accuracy and precision in paragraphs (c)(4) and (5) are met. Examples of possible changes include but are not limited to: introduction of a new chemical substance to the workplace which may interfere with the analysis of the new chemical; introduction of light to the workplace which may interfere with a light-sensitive SNUN substance; or introduction of water/increased humidity to the workplace which could react with the SNUN substance and cause difficulties in collection and analysis.

(9) Comparability. All data and results must be reported in the same units of measurement as the NCEL.

(10) Responsibility for Method Validity. The independent laboratory verification and EPA receipt of the sampling and analytical method pursuant to this subsection (c) do not ensure that the method will produce valid exposure monitoring data. The Company is ultimately responsible for ensuring the validity of its exposure monitoring data.

(d) Monitoring Potential Exposure.

(1) General.

(i) Action Level. The "action level" is defined as an airborne concentration of the SNUN substance, calculated as an 8-hour time-weighted average, equal to one half the NCEL

TWA specified in subparagraph (b)(1). For non-8-hour work shifts, the action level is equal to one half the NCELn. (The NCELn is described in subparagraph (b)(1)(ii).) The Company may exceed the action level without penalty. The purpose of the action level is solely to determine the requisite monitoring frequency.

(ii) Representative Exposure Groups. Whenever exposure monitoring is required by this New Chemical Exposure Limit section, the Company must take representative samples of what the potential exposure of each person who is reasonably likely to be exposed to airborne concentrations of the SNUN substance would be if respirators were not worn. The Company must do so by sampling the breathing zone air of at least one person that represents, and does not underestimate, the potential exposure of every person performing the same or substantially similar operations in each work shift, in each job classification, in each work area (hereinafter identified as an "exposure group") where inhalation exposure to the SNUN substance is reasonably likely to occur. The exposure of each person need not he itself directly sampled if that exposure is represented by sampling the exposure of another person in the same exposure group.

(iii) Good Laboratory Practice Standards. Determinations of potential inhalation exposure must be made according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and the sampling and analytical method developed pursuant to subsection (c) of this New Chemical Exposure Limit section. (Certain provisions of the TSCA GLPS applicable to toxicity testing in laboratory animals, such as 40 CFR 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are clearly inapplicable to the NCEL requirements.). However, compliance with TSCA GLPS is not required where exposure monitoring samples are analyzed by a laboratory accredited by either: (A) the AIHA IHLAP; or (B) another comparable program approved in advance in writing by EPA.

(iv) Full Shift Exposure Samples. Representative 8-hour TWA airborne concentrations must be determined on the basis of samples representing the full shift exposure for each exposure group.

(2) Initial Monitoring. Before the Company may deviate from the respirator requirements of the Protection in the Workplace section, the Company must conduct initial exposure monitoring to accurately determine the airborne concentration of the SNUN substance for each exposure group in which persons are reasonably likely to be exposed to the SNUN substance.

(3) Periodic Monitoring.

(i) If any representative samples taken during the initial exposure monitoring reveal an airborne concentration at or above the action level but at or below the TWA, the Company must repeat the exposure monitoring for that exposure group at least every 6 months. If the SNUN substance is not manufactured, processed, or used at all during a given 6 month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the SNUN substance is resumed. However, cessation of manufacturing, processing and use of the SNUN substance for less than the 6 month period does not constitute grounds for postponement of the 6 month deadline to conduct exposure monitoring.

(ii) If any representative samples taken during the initial exposure monitoring reveal an airborne concentration above the TWA, the Company must repeat the exposure monitoring for that exposure group at least every 3 months. If the SNUN substance is not manufactured, processed, or used at all during a given 3 month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the SNUN substance is resumed. However, cessation of manufacturing, processing and use of the SNUN

substance for less than the 3 month period does not constitute grounds for postponement of the 3 month deadline to conduct exposure monitoring.

(iii) The Company may alter the exposure monitoring schedule from every 3 months to every 6 months for any exposure group for whom two consecutive measurements taken at least 7 days apart indicate that the potential exposure has decreased to the TWA or below, but is at or above the action level. Where the SNUN substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(4) Termination of Monitoring.

(i) If representative samples taken during the initial exposure monitoring reveal an airborne concentration below the action level, the Company may discontinue monitoring for that exposure group, except when additional exposure monitoring is required by paragraph (d)(5) of this New Chemical Exposure Limit section.

(ii) If representative samples taken during the periodic monitoring reveal that an airborne concentration, as indicated by at least 2 consecutive measurements taken at least 7 days apart, are below the action level, the Company may discontinue the monitoring for that exposure group, except when additional monitoring is required by paragraph (d)(5) of this New Chemical Exposure Limit section. Where the SNUN substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(5) Additional Monitoring.

(i) For a previously monitored exposure group, the Company must, within 7 days of any of the events listed below in this paragraph (d)(5)(i), conduct the initial exposure monitoring followed by any periodic or additional exposure monitoring required by subsection (d) of this New Chemical Exposure Limit section:

(I) change in the production volume, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the SNUN substance;

(II) spills, leaks, ruptures or other breakdowns occur that may reasonably cause new or additional exposures to the SNUN substance; and

(III) whenever else the Company has any reason to suspect a change that may reasonably result in new or additional exposures to the SNUN substance.

(ii) In no event is the additional exposure monitoring requirement in paragraph (d)(5)(i) intended to delay implementation of any necessary cleanup or other remedial action. During any cleanup or remedial operations that may occur before commencing additional exposure monitoring, the Company must ensure that potentially exposed persons use at least the respiratory protection specified in subsection (e) for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

(6) Notification of Monitoring Results.

(i) Within 15 working days after receipt of the results of any exposure monitoring required by this Order, the Company must notify each person whose exposure is represented by that monitoring. The notice must identify the NCEL, the exposure monitoring results, and any corresponding respiratory protection required by subsection (e). Affected persons must be notified

in writing either individually or by posting the information in an appropriate and accessible location.

(ii) Whenever the NCEL is exceeded, the written notification required by the preceding paragraph must describe the action being taken by the Company to reduce inhalation exposure to or below the NCEL, or must refer to a document available to the person which states the actions to be taken to reduce exposure.

(7) Exemption based on Objective Data. Where the Company has documented and reliable objective data demonstrating that, even under worst-case conditions, Worker exposure to the SNUN substance will not exceed the action level (defined in paragraph (d)(1)(i)) under the expected handling procedures and conditions for a specific "exposure group" (defined in paragraph (d)(1)(ii)), then that exposure group is exempt from this New Chemical Exposure Limit section (except paragraph (d)(5) "Additional Monitoring" and subsection (f) "NCEL Recordkeeping") and the respirator requirements in the Protection in the Workplace section of this Order. Any such objective data must accurately characterize actual Worker exposures to the SNUN substance and must be obtained under conditions closely resembling the types of materials, processes, control methods, work practices, and environmental conditions in the Company's current workplace operations with the SNUN substance. Examples of objective data that may be used to demonstrate that Worker exposure will not exceed the action level, even under worst case conditions, include information on the physical and chemical properties of the SNUN substance, industry-wide studies, and/or laboratory test results.

(e) Respiratory Protection.

(1) General. Whenever the Company has conducted exposure monitoring at a workplace in accordance with subsection (d) of this New Chemical Exposure Limit section and the measured

airborne concentration of the SNUN substance for any person who is reasonably likely to be exposed to the SNUN substance by inhalation exceeds the NCEL, the Company must provide those persons the respirators specified in this subsection (e) (rather than the respirator(s) identified in the Protection in the Workplace section of this Order), and must ensure that the respirators are used (including training, fit testing, and maintenance) in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. When the Company has not yet measured the airborne concentration of the SNUN substance at a workplace in accordance with this New Chemical Exposure Limit section, the Company must comply with the respirator requirements in the Protection in the Workplace section of this Order at that workplace.

(2) Selection of Appropriate Respiratory Protection. After the Company has conducted exposure monitoring in accordance with subsection (d) of this New Chemical Exposure Limit section, the Company must select, provide, and ensure that persons who are reasonably likely to be exposed to the SNUN substance by inhalation use, at a minimum, the respiratory protection which corresponds in the following table to the measured airborne concentration (or a more protective respirator which corresponds to a concentration higher than measured).

PARTICULATE RESPIRATOR TABLE

Measured Concentration of SNUN Substance	**Required Respiratory Protection**
≤ NCEL	No respiratory protection is required.
≤ 50 x NCEL	(I) Any NIOSH-certified **air-purifying** full facepiece respirator equipped with N100 (if oil aerosols absent), R-100, or P-100 filter(s).

(II) Any NIOSH-certified **powered air-purifying** respirator equipped with a tight-fitting facepiece (full facepiece) and equipped with HEPA filters.

(III) Any NIOSH-certified negative pressure (demand) **supplied-air** respirator equipped with a full facepiece.

(IV) Any NIOSH-certified continuous flow **supplied-air** respirator equipped with a tight-fitting facepiece (full facepiece).

(V) Any NIOSH-certified negative pressure (demand) **self-contained breathing apparatus** (SCBA) equipped with a hood or helmet or a full facepiece.

(3) Reductions in Respiratory Protection. After appropriate respiratory protection has been selected based on the results of actual exposure monitoring conducted at a workplace in accordance with subsection (d) of this New Chemical Exposure Limit section, the Company must not, at that workplace, use the respiratory protection required by the Protection in the Workplace section of this Order (unless it is the same as required by this New Chemical Exposure Limit section). Before the Company may make any reduction in any respiratory protection selected pursuant to this New Chemical Exposure Limit section, the Company must verify, by 2 consecutive measurements taken at least 7 days apart, that the new respiratory protection is appropriate in accordance with paragraph (e)(2). Where the SNUN substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(4) Special Situations.

(i) Measurements Outside Quantitation Limits. When a value less than the LQL of the analytical method (as described in paragraph (c)(4)(ii)) is measured, the Company must estimate potential exposure using generally established and accepted statistical methods. If the

Company obtains an exposure monitoring sample that is more than 10% above the actual UQL of the analytical method, the Company must ensure that its workers wear at least a NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece. Any reductions in this respiratory protection must comply with paragraph (e)(3). The Company may submit an improved analytical method provided that it complies fully with subsection (c) of this New Chemical Exposure Limit section, including the verification required by subsection (c)(3).

(ii) Cleanup and Remedial Actions. During any special cleanup or other remedial actions that may occur before commencing additional exposure monitoring (as discussed in paragraph (d)(5)(ii)), the Company must ensure that potentially exposed persons use at least the respiratory protection specified above in this subsection (e) for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

(f) NCEL Recordkeeping.

(1) Whenever the Company elects to comply with this New Chemical Exposure Limit section rather than the respirator requirements in the Protection in the Workplace section of this Order, the Company must maintain the following records until 30 years after the date they are created, and must make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(i) A copy of the sampling and analytical methods used and continuing evidence of their accuracy over time as required by section (c);

(ii) Records documenting compliance with the analytical method verification requirements of subsection (c)(3), including copies of the signed certification statement and the verification results obtained by both laboratories;

(iii) Records documenting either compliance with the Good Laboratory Practice Standards at 40 CFR Part 792, or use of a laboratory accredited by the AIHA or another comparable program approved in advance in writing by EPA. Where the Company elects to not comply with TSCA GLPS, such records must include the written accreditation from the AIHA or the written approval from EPA.

(iv) Records documenting all exposure monitoring dates, duration, and results of each sample taken;

(v) Records documenting the name, address, work shift, job classification, and work area of the person monitored and of all other persons whose exposures the monitoring is intended to represent;

(vi) Any conditions that might have affected the monitoring results;

(vii) Notification of exposure monitoring results required by paragraph (d)(6);

(viii) Records documenting any changes in the production, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the SNUN substance;

(ix) Records documenting any spills, leaks, ruptures or other breakdowns that may cause new or additional exposure;

(x) The type of respiratory protective devices worn by the monitored person, if any;

(xi) Records documenting any actions taken to mitigate exposures to the SNUN substance;

(xii) Records documenting reliance on the objective data exemption in paragraph (d)(7), including: (A) the source of the data, (B) protocols and results of any relevant testing or analysis, (C) a description of the operation exempted and how the data demonstrate that worker exposures will not exceed the action level, (D) other data relevant to the operations, materials and worker exposures covered by the exemption.

HAZARD COMMUNICATION PROGRAM

(a) Written Hazard Communication Program. The Company must develop and implement a written hazard communication program for the SNUN substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, SDSs or MSDSs, and other forms of warning material will be satisfied. The Company must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Company may rely on an existing hazard communication program, including an existing program established under the OSHA Hazard Communication Standard (29 C.F.R. § 1910.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program must include the following:

(1) A list of chemical substances known to be present in the work area which are subject to a consent order or order issued under § 5 of TSCA to the Company, or to a significant new use rule ("SNUR") issued under § 5(a)(2) of TSCA and 40 C.F.R. pt. 721, subpt. E. The list must be maintained in each work area where the SNUN substance is known to be present and must use the identity provided on the SDS or MSDS for the SNUN substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the

Company is required either by another consent order or order issued under § 5 of TSCA, or by a SNUR issued under TSCA § 5(a)(2) and 40 C.F.R. pt. 721, subpt. E, to maintain a list of substances, the lists must be combined with the list under this subparagraph.

(2) The methods the Company will use to inform employees of the hazards of non-routine tasks involving the SNUN substance (e.g., cleaning of reactor vessels), and the hazards associated with the SNUN substance contained in unlabeled pipes in their work area.

(3) The methods the Company will use to inform contractors of the presence of the SNUN substance in the Company's workplace and of the provisions of this Consent Order if employees of the contractor work in the Company's workplace and are reasonably likely to be exposed to the SNUN substance while in the Company's workplace.

(b) Labeling.

(1) The Company must ensure that each container of the SNUN substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label must, at a minimum, contain the following information:

(A) A statement of the health hazards(s) and precautionary measure(s) identified in paragraph (f) of this section. These statements may be supplemented with any health hazard(s) and precautionary measure(s) identified by the Company.

(B) The identity by which the SNUN substance may be commonly recognized.

(C) A statement of the environmental hazards(s) and precautionary measure(s) identified in paragraph (f) of this section. These statements may be supplemented with any environmental hazard(s) and precautionary measure(s) identified by the Company.

(D) A statement of exposure and precautionary measure(s), if any, identified either in paragraph (f) of this section. These statements may be supplemented with any exposure and precautionary measure(s) identified by the Company

(ii) The Company may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Company need not label portable containers into which the SNUN substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Company must not remove or deface an existing label on containers of the SNUN substance obtained from persons outside the Company unless the container is immediately re-labeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Company must ensure that each container of the SNUN substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label must, at a minimum, contain the following information:

(A) The information prescribed in subparagraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the SNUN substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label must not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, must be legible and prominently displayed.

(4) The label, or alternative forms of warning, must be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the SNUN substance in combination with any other substance that is either subject to another consent order or order issued under § 5 of TSCA to the Company, SNUR issued under § 5(a)(2) of TSCA and 40 C.F.R. pt. 721, subpt. E, or defined as a "hazardous chemical" under the OSHA Hazard Communication Standard (29 C.F.R. § 1910.1200), the Company may prescribe on the label, SDS or MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Company determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Consent Order, the Company must seek a determination of equivalency for such alternative control measures pursuant to 40 C.F.R. § 721.30 before prescribing them under this subparagraph (b)(5).

(6) If the Company becomes aware of any significant new information regarding the hazards of the SNUN substance or ways to protect against the hazards, this new information must be added to the label within 3 months from the time the Company becomes aware of the new information. If the SNUN substance is not being manufactured (defined by statute to include import), processed, or used in the Company's workplace, the Company must add the new information to the label before the SNUN substance is reintroduced into the workplace.

(c) Safety Data Sheets or Material Safety Data Sheets.

(1) The Company must obtain or develop an SDS or MSDS for the SNUN substance.

(2) The SDS or MSDS must contain, at a minimum, the following information:

(i) The identity used on the container label of the SNUN substance under this section, and, if not claimed confidential, the chemical and common name of the SNUN substance. If the chemical and common names are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the SNUN substance known to the Company, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the SNUN substance known to the Company, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (f) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the SNUN substance known to the Company.

(vi) The primary routes of exposure to the SNUN substance.

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Consent Order, or alternative control measures which EPA has determined under 40 C.F.R. § 721.30 provide substantially the same degree of protection as the identified control measures. The SDS or MSDS must identify any New Chemical Exposure Limits specified in paragraph (b) of the New Chemical Exposure Limit section of this Consent Order and must contain the information specified in the graduated respirator table in paragraph (e)(2) of the New Chemical Exposure Limit section.

(viii) Any generally applicable precautions for safe handling and use of the SNUN substance which are known to the Company, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Company, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Company.

(xi) The date of preparation of the SDS or MSDS or of its last revision.

(xii) The name, address, and telephone number of the Company or another responsible party who can provide additional information on the SNUN substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the SDS or MSDS, the Company must mark the SDS or MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the SNUN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Company may prepare one SDS or MSDS to apply to all of these multiple mixtures.

(5) If the Company becomes aware of any significant new information regarding the hazards of the SNUN substance or ways to protect against the hazards, this new information must be added to the SDS or MSDS within 3 months from the time the Company becomes aware of the new information. If the SNUN substance is not being manufactured (defined by statute to include

import), processed, or used in the Company's workplace, the Company must add the new information to the SDS or MSDS before the SNUN substance is reintroduced into the workplace.

(6) The Company must ensure that persons receiving the SNUN substance from the Company are provided an appropriate SDS or MSDS with their initial shipment and with the first shipment after an SDS or MSDS is revised. The Company may either provide the SDS or MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Company must maintain a copy of the SDS or MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The SDS or MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the SNUN substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The SDS or MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee Information and Training. The Company must ensure that employees are provided with information and training on the SNUN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the SNUN substance and whenever the SNUN substance is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph must include:

(i) The requirements of this section.

(ii) Any operations in the work area where the SNUN substance is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and SDSs or MSDSs required hy paragraph (e) of this section.

(2) The training provided to employees must include:

(i) Methods and observations that may bc used to detect the presence or release of the SNUN substance in or from an employee's work area (such as exposure monitoring conducted by the Company, continuous monitoring devices, visual appearance, or odor of the SNUN substance when being released).

(ii) The potential human health and environmental hazards of the SNUN substance as specified in paragraph (f) of this scction.

(iii) The measures employees can take to protect themselves and the environment from the SNUN substance, including specific procedures the Company has implemented to protect employees and the environment from exposure to the SNUN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Consent Order, or alternative control measures which EPA has determined under 40 C.F.R. § 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Company under this scction, including an explanation of the labeling system and the SDS or MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) *De Minimis* Concentrations. The requirements of this section do not apply to quantities of the SNUN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the SNUN substance is identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Consent Order). This exemption is not available if the Company has reason to believe that, during intended activities, the SNUN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies. If this Consent Order contains New Chemical Exposure Limits provisions or Release to Water provisions that, respectively, specify a NCEL concentration ("TWA") or in-stream concentration ("N") less than the *de minimis* concentration specified here, then this *de minimis* exemption does not apply.

(f) Human Health, Environmental Hazard, Exposure, and Precautionary Statements. The following human health and environmental hazard and precautionary statements must appear on each label as specified in paragraph (b) and the SDS or MSDS as specified in paragraph (c) of this section:

(1) Human health hazard statements. This substance may cause:

(i) internal organ effects.

(ii) cancer.

(iii) immune system effects.

(2) Human hazard precautionary statements. When using this substance:

(i) avoid skin contact.

(ii) avoid breathing the substance.

(iii) avoid ingestion.

(iv) use respiratory protection, or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.05 mg/m^3.

(v) use skin protection.

(3) Environmental hazard statements. This substance may be:

(i) toxic to fish.

(ii) toxic to aquatic organisms.

(4) Environmental hazard precautionary statements. Notice to users:

(i) disposal restrictions apply.

(5) The human and environmental hazard and precautionary statement on the label prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the SDS or MSDS for details."

(6) The Company may use alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard.

(g) Existing Hazard Communication Program. The Company need not take additional actions if existing programs and procedures satisfy the requirements of this section.

DISTRIBUTION

(a) Export Notice Requirement. No later than the date of distribution, the Company must notify in writing any person to whom it distributes the SNUN substance that, due to the issuance of this Consent Order and the SNUR at 40 CFR 721.5549, the SNUN substance is subject to the export notification requirements of TSCA § 12(b) and 40 C.F.R. Part 707, Subpart D. Such notice must

contain, in the form in which it appears in this Consent Order, the following information: (1) the SNUN number, and (2) either (A) the specific chemical identity of the SNUN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(b) Distribution Requirements. Except as provided in paragraph (c), the Company is permitted to distribute the SNUN substance outside the Company, other than for disposal, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Notify in writing any person to whom it distributes the SNUN substance that, due to the issuance of this Consent Order under § 5(e) of TSCA and the SNUR at 40 CFR 721.5549, the SNUN substance is subject to the export notification requirements of TSCA § 12(b) and 40 C.F.R. Part 707, Subpart D. Such notice must contain, in the form in which it appears in this Consent Order, the following information: (1) the SNUN number, and (2) either (A) the specific chemical identity of the SNUN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(2) Comply with the same requirements and restrictions required of the Company in the Protection in the Workplace section, or, as an alternative to the respirator requirements in the Protection in the Workplace Section, the New Chemical Exposure Limit sections of this Consent Order.

(3) Comply with the same requirements and restrictions required of the Company in the Hazard Communication Program section of this Consent Order.

(4) Comply with the same environmental release restrictions required of the Company in the Release to Water sections of this Consent Order.

(c) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the SNUN substance, the Company obtains knowledge that a recipient of the SNUN substance has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section or, after paragraph (b) expires in accordance with subparagraph (e)(1), has engaged in a significant new use of the SNUN substance (as defined in 40 C.F.R. Part 721, Subpart E) without submitting a significant new use notice to EPA, the Company must cease supplying the SNUN substance to that recipient, unless the Company is able to document each of the following:

(1) That the Company has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the SNUN substance without submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (b) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rule for the SNUN substance and will not engage in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (d)(2) of this Distribution section, the Company obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the SNUN substance without submitting a significant new use notice to EPA, the Company must cease supplying the SNUN substance to that recipient, must notify EPA of the failure to comply, and is permitted to resume supplying the SNUN substance to that recipient only upon written notification from the Agency.

(d) Sunset Following SNUR and Notification of SNUR. (1) Paragraphs (b) and (c) of this Distribution section will expire 75 days after promulgation of a final modified SNUR for the SNUN substance under § 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, paragraphs (h) and (c) of this Distribution section will not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have heen resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final modified SNUR for the SNUN substance and paragraph (b) of this Distribution section expires in accordance with subparagraph (e)(1), the Company must notify each person to whom it distributes the SNUN substance of the existence of the modified SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would require significant new use notification to EPA for the SNUN substance. Such notice must also reference the publication of the SNUR for this SNUN substance in either the Federal Register or the Code of Federal Regulations.

RELEASE TO WATER

(a) This provision does not supersede or preempt any applicable federal, state, and local laws and regulations. (Those other laws may be more stringent than the requirements below.) The Company is prohibited from any predictable or purposeful release of the SNUN substance, or any waste stream from manufacturing, processing or use) containing the SNUN substance:

(1)(i) Into the waters of the United States if the quotient from the formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = \text{N parts per billion}$$

exceeds 1 ppb, when calculated using the methods described in 40 C.F.R. § 721.91.

(ii) In lieu of calculating the quotient in subparagraph (1)(i), monitoring or alternative calculations may be used to predict the surface water concentration expected to result from the intended release of the SNUN substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on a written request to approve monitoring procedures or alternative calculations within 90 days after such a request is received. The Agency will inform the Company of the disposition of such requests in writing and, where a request is denied, will explain the reasons therefore.

(b) Predictable or Purposeful Releases. (1) If for any reason the Company fails to comply with the strict release limitations applicable to the SNUN substance under this "Release to Water" section, the Company shall notify EPA within 5 days of the release. If the Company believes that a given release was not predictable or purposeful it shall provide in writing to EPA an explanation and description of the reasons for the release; the amount of the release; all actions taken or to be taken to prevent or minimize the release or future releases; a schedule for implementation of any measures to be taken to prevent or mitigate effects of the release; the Company's rationale for attributing such release to non-predictable or non-purposeful causes; and a statement as to whether, in the opinion of the Company, such release may cause or contribute to an endangerment to public health or welfare, or the environment. The Company shall include with any notice all available

documentation supporting their claim that the release was not predictable or purposeful. If EPA agrees that the release to water was not predictable or purposeful, it may excuse the release.

(2) Routine or repeated activity that results in releases to water or non-routine releases to water that are not due to emergency conditions are predictable or purposeful. EPA does not intend the phrase "predictable or purposeful" to limit EPA's strict liability authority under TSCA.

III. RECORDKEEPING

(a) Records. The Company must maintain the following records until 5 years after the date they are created and must make them available for inspection and copying by EPA in accordance with § 11 of TSCA:

(1) Exemptions. Records documenting that the SNUN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Consent Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the SNUN substance eligible for the export only exemption in Section I, Paragraph (b)(1) of this Consent Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA §§ 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the SNUN substance eligible for the research and development exemption in Section I, Paragraph (b)(2) of this Consent Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 C.F.R. § 721.125. For any amounts or batches of the SNUN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Consent Order, the Company must keep records

demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture (which includes import) volume of the SNUN substance and the corresponding dates of manufacture;

(3) Records documenting the names and addresses (including shipment destination address, if different) of all processors outside the site of manufacture (which includes import) to whom the Company directly sells or transfers the SNUN substance, the date of each sale or transfer, and the quantity of the SNUN substance sold or transferred on such date;

(4) Records documenting the address of all sites of manufacture (which includes import), processing, and use;

(5) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Consent Order;

(6) Records documenting the determinations required by the Protection in the Workplace section of this Consent Order that chemical protective clothing is impervious to the SNUN substance;

(7) Records required by paragraph (f). of the New Chemical Exposure Limits section of this Consent Order, if applicable;

(8) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Consent Order;

(9) Copies of labels required under the Hazard Communication Program section of this Consent Order;

(10) Copies of Material Safety Data Sheets required by the Hazard Communication Program section of this Consent Order;

(11) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, and Distribution sections of this Consent Order, including distributees' written agreement to comply with the Distribution section of this Consent Order;

(12) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Consent Order;

(13) Copies of any Transfer Documents and notices required by the Successor Liability section of this Consent Order, if applicable; and,

(14) The Company must keep a copy of this Consent Order at each of its sites where the SNUN substance is manufactured (which includes import).

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 C.F.R. Part 1320, particularly 5 C.F.R. § 1320.5(b), the Company is not required to respond to this "collection of information" unless this Consent Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Company. The

"collection of information" required in this TSCA § 5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to § 11 of TSCA, 40 C.F.R. § 720.122 and 40 C.F.R. § 721.35 EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the SNUN substance. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request include, but are not limited to, the following:

(1) Expected dates and times when the SNUN substance will be in production within the subsequent 12 months;

(2) Current workshift schedules for workers who are involved in activities associated with the SNUN substance and may reasonably be exposed to the SNUN substance;

(3) Current job titles or categories for workers who are involved in activities associated with the SNUN substance and may reasonably be exposed to the SNUN substance;

(4) Existing exposure monitoring data for workers who are involved in activities associated with the SNUN substance and may reasonably be exposed to the SNUN substance;

(5) Records required by the Recordkeeping section of this Consent Order; and/or,

(6) Any other information reasonably related to determining compliance with this Consent Order or conducting an inspection for that purpose.

(b) Company's Response. The Company must respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response must be in writing. To the extent the information is known to or reasonably ascertainable by the Company at the time of the request, the Company's response must demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) will be protected in accordance with §14 of TSCA and 40 C.F.R. Part 2, Subpart B. In order to make a confidentiality claim for information submitted to EPA, an authorized official of the Company must certify that it is true and accurate that the Company has:

(1) Taken reasonable measures to protect the confidentiality of the information;

(2) Determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(3) A reasonable basis to conclude that the disclosure of the information is likely to cause substantial harm to the competitive position of the Company; and

(4) A reasonable basis to believe that the information is not readily discoverable through reverse engineering.

CBI claims for chemical identity must be accompanied by a generic chemical identity, which may be that used for the SNUN. CBI claims must be accompanied by substantiations in accordance with TSCA § 14(c)(5). Guidance on substantiating CBI claims may be found at https://www.epa.gov/tsca-cbi/substantiating-cbi-claims-under-tsca-time-initial-submission.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Consent Order may be transferred when the Company transfers its interests in the SNUN substance, including the right to manufacture the SNUN substance for the significant new use to another person outside the Company (the "Successor in Interest").

(b) Requirements of the Transfer.

The Successor in Interest must comply with the terms of this Consent Order and will not be required to submit a new SNUN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Consent Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the SNUN substance for the significant new use, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the SNUN substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the SNUN substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 C.F.R. § 720.22(a)(3) and 40 C.F.R. § 720.3(z).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the SNUN substance, including the right to manufacture the SNUN substance for the significant new use, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company must provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment B to this Consent Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company must submit the fully executed Notice of Transfer document to EPA as a support document for the SNUN, using the procedures set out in 40 C.F.R. § 720.40.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the SNUN substance is manufactured. Copies of the Transfer Document must also be made available for inspection pursuant to § 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the SNUN substance under the terms of this Consent Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company will be liable for compliance with the requirements of this Consent Order until the effective date of the transfer described above.

(2) The Successor in Interest will be liable for compliance with the requirements of this Consent Order effective as of the date of transfer.

(3) Nothing in this section may be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the SNUN substance pursuant to the terms of this Consent Order.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Consent Order may be modified only via the procedures in this Section. The Company may request in writing at any time, based upon new information on the human health or environmental effects of, or human exposure to or environmental release of, the SNUN substance, that EPA agree to modify or revoke substantive provisions of this Consent Order, including, but not limited to, testing requirements, workplace protections, disposal requirements, or discharge limits. The exposures and risks identified by EPA during its review of the SNUN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Consent Order. However, in determining whether to amend or revoke the substantive provisions of this Consent Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Consent Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities described therein are no longer necessary to protect against an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the SNUN substance.

In addition, the Company may request in writing at any time that EPA make other modifications to the language of this Consent Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Consent Order as issued.

VII. EFFECT OF CONSENT ORDER

(a) Waiver. By consenting to the entry of this Consent Order, the Company waives its rights to receive service of this Consent Order no later than 45 days before the end of the applicable review period pursuant to § 5(e)(1)(B) of TSCA and to challenge the validity of this Consent Order in any subsequent action. Consenting to the entry of this Consent Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

(b) Effective Date. This Consent Order shall be effective upon the expiration of the SNUN review period after the EPA's receipt of a fully executed copy of the Consent Order. The EPA will notify the Company of its receipt of the fully executed copy of the Consent Order.

03/27/19
Date

Tala R. Henry, Ph.D.
Acting Deputy Director for Programs
Office of Pollution Prevention and Toxics

4/7/19
Date

[redacted]

ATTACHMENT A

DEFINITIONS

[Note: The attached Consent Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Consent Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture (which includes import) the SNUN substance under the conditions specified in Section II of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Intermediate" means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of another chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rates of such chemical reactions.

"Manufacture" means to produce or manufacture in the United States or import into the customs territory of the United States.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured or processed.

"SNUN substance" means the chemical substance described in the significant new use notice submitted by the Company relevant to this Consent Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Predictable or Purposeful Releases" means the routine or repeated activity that results in non-routine releases to water or non-routine releases to water that are not due to emergency conditions. EPA does not intend the "predictable or purposeful to limit the agency's strict liability authority under TSCA.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-reviewed protocol or the Good Laboratory Practice Standards at 40 C.F.R. Part 792 without prior or subsequent Agency review that prevents a reasoned evaluation of the health or environmental effects of the SNUN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-reviewed protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the SNUN substance.

"SDS" means safety data sheet, the written listing of data for the chemical substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the SNUN substance, and from which there will be no human exposure to, nor environmental release of, the SNUN substance during transport and storage.

"Site-limited intermediate" means an intermediate manufactured, processed, and used only within a site and not distributed in commerce other than as an impurity or for disposal. Imported intermediates cannot be "site-limited."

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 C.F.R. § 122.2.

"Work area" means a room or defined space in a workplace where the SNUN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

NOTICE OF TRANSFER
OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

_____ _____ _____
Company (Transferor) SNUN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice ("SNUN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substances Control Act ("TSCA," 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the SNUN substance, will be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 C.F.R. § 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 C.F.R. Part 2, for the SNUN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation will be deemed to apply to all such claims. Where "modifies" is indicated, such modification will be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

In order to make a confidentiality claim for information submitted to EPA, an authorized official of the Successor in Interest must certify that it is true and accurate that the Successor in Interest has:

(1) Taken reasonable measures to protect the confidentiality of the information;

(2) Determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(3) A reasonable basis to conclude that the disclosure of the information is likely to cause substantial harm to the competitive position of the Successor in Interest; and

(4) A reasonable basis to believe that the information is not readily discoverable through reverse engineering.

CBI claims for chemical identity must be accompanied by a generic chemical identity, which may be that used for the SNUN.

NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

(continued)

Company (Transferor) SNUN Number

Signature of Authorized Official Date

Printed Name of Authorized Official

Title of Authorized Official

Successor in Interest

Signature of Authorized Official Date

Printed Name of Authorized Official

Title of Authorized Official

Address

City, State, Zip Code

NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER
(continued)

_____
Successor's Technical Contact

_____
Address

_____
City, State, Zip Code

_____
Phone

ATTACHMENT C

STATISTICAL ANALYSIS OF NCELs ANALYTICAL METHOD VERIFICATION RESULTS

This Attachment describes the statistical technique (with examples) for comparing the analytical results obtained by two laboratories pursuant to paragraph (c)(3)(vii) of the New Chemical Exposure Limit section of this Order.

STATISTICAL TECHNIQUE

To obtain two-sample t test with unequal variances, perform the following operations:

- Compute means of the data measured by two laboratories.
- Compute mean squares

$$S_i^2 = \sum(\bar{X}_{ij} - X_i)^2/(n_i - 1),\ i=1, 2$$

- Form the ratio

$$T = (\bar{X}_1 - \bar{X}_2)/(W_1 + W_2)^{1/2}$$

- Compute degrees of freedom

$$f = (W_1 + W_2)^2/[W_1^2/(n_1 - 1) + W_2^2/(n_2 - 1)]$$

where,

$W_1 = S_1^2/n_1,\ i = 1, 2$

$\bar{X}_1$ = Average of the results from the company laboratory

$\bar{X}_2$ = Average of the results from the independent laboratory

n_1 = Number of samples analyzed by the company laboratory

n_2 = Number of samples analyzed by the independent laboratory.

Then compare the absolute value of T to the 97.5 percentile point of a t distribution with f degrees of freedom. If the absolute value exceeds the 97.5 percentile point, the results measured by two laboratories are significantly different at 95% level. Otherwise, they are not significantly different. In general, f may not be an integer. Use interpolation to obtain the 97.5 percentile point of a t distribution with f degrees of freedom.

EXAMPLES -- The following examples (based on simulated data) illustrate the method:

Example 1

Data Set 1	Data Set 2
80.56	97.11
100.01	102.13
86.04	99.83
52.61	97.83
84.85	105.44
95.75	100.04

$\bar{X}_1 = 83.30$ $n_1 = 6$ $\bar{X}_2 = 100.40$ $n_2 = 6$

$S_1^2 = 278.72$ $W_1 = 46.25$ $S_2^2 = 9.26$ $W_2 = 1.54$

Absolute value of $T = 2.467$ $f = 5.33$

The t table shows that the 97.5 percentile point is 2.571 and 2.447 for 5 and 6 degrees of freedom, respectively. For 5.33 degrees of freedom, the 97.5 percentile point will be approximately 2.530 which is greater than the absolute value of T, 2.467. Hence, the means of two data sets are not significantly different at the 5% level.

However, if this problem had been treated as an ordinary two-sample t test, the means would be significantly different at the 5% level because the absolute of T is greater than 2.228, the 97.5 percentile point for the t distribution with 10 degrees of freedom.

Example 2

Data Set 1	Data Set 2
82.87	108.05
101.85	96.51
87.44	100.04
99.68	104.33
101.15	110.32
99.21	107.00

$\bar{X}_1 = 95.37$	$n_1 = 6$	$\bar{X}_2 = 104.37$	$n_2 = 6$
$S_1^1 = 65.59$	$W_1 = 10.93$	$S_2^2 = 27.25$	$W_2 = 4.54$
Absolute value of $T = 2.290$		$f = 8.54$	

The t table shows that for 8 and 9 degrees of freedom the 97.5 percentile point is 2.306 and 2.262, respectively. For 8.54 degrees of freedom the 97.5 percentile point will be approximately 2.282 which is less than the absolute value of T, 2.290. Hence, the means of two data sets are significantly different at the 5% level.