TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

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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:	)	Premanufacture Notice Numbers:
	)	
	)	
	)	
	)	EPA SANITIZED
	)	
[redacted]	)	P-16-0356 and P-16-0357
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Consent Order and Determinations Supporting Consent Order

[redacted]

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PREAMBLE

I. INTRODUCTION

This Consent Order is entered into voluntarily by the Environmental Protection Agency ("EPA" or "the Agency") and [redacted] ("the Company"), regarding premanufacture notices ("PMNs") P-16-356 [redacted] and P-16-357 [redacted] ("the PMN substances"). The Consent Order is issued under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. § 2604(e)). The Company submitted the PMNs to EPA pursuant to § 5(a)(1)(B) of TSCA and 40 C.F.R. pt. 720.

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 Consent Order requires the Company to:

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

(b) refrain from manufacturing, processing or using the PMN substance in a manner that generates a vapor, mist, or aerosol;

(c) refrain from using the PMN substances other than as described in the PMN [redacted]

[redacted]

(d) distribute the PMN substances only to a person who agrees to follow the same restrictions (except the testing requirements); and,

(e) maintain certain records.

III. CONTENTS OF PMNs

By signing the 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 Consent Order): Submitter information, chemical identity, production volume, use, industrial sites, manufacturing, worker activities, protective equipment, physical form, number of workers, environmental releases, and physical and chemical properties

Chemical Identity:

Specific:

P-16-356 [redacted]

P-16-357 [redacted]

Generic: Quaternary ammonium salts

Use:

Specific: [redacted]

Generic: Wellbore additive

Maximum Estimated 12-Month Production Volume: P-16-356 [redacted] and P-16-357 [redacted]

Test Data Submitted with PMN: 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 PMN substances, based on the information currently available to the Agency.

Human Health Effects Summary:

Absorption: For both PMN substances, absorption is nil through the skin as the neat material, poor through the skin when in solution and poor through the lungs and GI tract (pchem).

Toxicological Endpoints of Concern: irritation, lung effects, and neurotoxicity

Basis: For both PMN substances, there is concern for irritation to all exposed tissues based on warnings in the SDS and the pH. There is also concern for lung effects if inhaled based on the surfactant properties. There is uncertain concern for neurotoxicity based on the potential release and absorption of smaller quaternary compounds.

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

Environmental Effects Summary:

Risks to the environment were low based on no exceedance of the acute concentration of concern (COC) of 880 pp and because the chronic COC of 31 ppb is exceeded less than 20 days. Ecotoxicity hazard concerns were moderate based on Structural Activity Relationship (SAR) nearest analog predictions for cationic surfactants.

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	Process	Use 1	Use 2
# Sites	[redacted]	[redacted]	[redacted]	[redacted]
Workers (#/site)	[redacted]	[redacted]	[redacted]	[redacted]
Exposure (days/year)	[redacted]	[redacted]	[redacted]	[redacted]
Dermal Exposure (mg/day)	[redacted]	[redacted]	[redacted]	[redacted]

Inhalation Exposure (mg/day)	Negligible	Negligible	Negligible	Negligible
Drinking Water Exposure (mg/kg/day)	[redacted]	[redacted]	[redacted]	[redacted]
Releases (days/year)				
Release to Water (kg/day)				
Surface Water Concentration (ppb)				
Days Exceeding Concern Level				

EPA estimates the substantial environmental release for total release after treatment of [redacted]. EPA estimates substantial human exposure from groundwater dose of [redacted]

Risk to Workers:

There are potential risks to workers for irritation, lung effects, and neurotoxicity, which can be mitigated by impervious gloves and negligible inhalation exposures.

Risk to General Public:

No risks to general public were identified.

Risk to Consumers:

No consumer use was identified.

V. EPA'S DETERMINATION

The following findings constitute the basis of this Consent Order, issued under § 5(e) of TSCA:

(a) EPA is unable to determine whether the PMN substances 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 PMN substances and that the PMN substances may cause harm to lungs if inhaled as well as possible environmental harm. Therefore, pursuant to §§ 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, EPA has determined that uncontrolled manufacture, processing, distribution in commerce, use, or disposal of the PMN substances may present an unreasonable risk of injury to health and the environment and that the limitations imposed by the Consent Order are necessary to protect against such risk.

(b) In light of the estimated production volume of, and human exposure to the PMN substance, EPA has determined, pursuant to §§ 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II) of TSCA, that the PMN substance will be produced in substantial quantities and that the PMN substance may reasonably be anticipated to enter the environment in substantial quantities and there may be significant human exposure to the PMN substance.

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Pended Testing. The Consent Order does not require submission of the following pended testing at any specified time or production volume.

Ecotoxicity Testing

- Fish Acute Toxicity Test, Freshwater and Marine — OPPTS Test Guideline 850.1075
- Aquatic Invertebrate Acute Toxicity Test — OPPTS Test Guideline 850.1010
- Algal toxicity test — OCSPP Test Guideline 850.4500

Human Health Testing

Tier I – Use physical-chemical properties to characterize lung exposure/disruption

- Particle Size Distribution or Aerosolized Droplet Size (OECD TG 110 or OPPTS 830.7520)
- Surface Tension Decreases (capillary surface tension method with appropriate controls)

Tier II- Proposed *In Vivo* Studies

- Step 1: OECD Acute TG 403 featuring rats exposed for 4 hours and observed for 2 weeks (LOAEC < 2000 mg/m^3, proceed to step 2)
- Step 2: 5-Day study to address toxicity progression (substantial decrease in the POD or increase in severity at the same concentration over time relative to the acute study, proceed to step 3)
- Step 3: OECD TG 412 (28-day inhalation study in rats with 14-day recovery period)

The Consent Order's restrictions on manufacture, processing, and use of the PMN substances will remain in effect until the Consent Order is modified or revoked by EPA based on submission of

this testing or other relevant information. This testing may be required if a modification is requested to deviate from the condition of the Consent Order

NOTE: Any request by EPA for the pended testing described in the 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 PMN substances. Further, any such testing request on the part of 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. In addition, consistent with § section 4(h)(1)(B)(ii) of TSCA, EPA has requested testing on only one of the PMN substances covered by the Consent Order because EPA has determined that testing on the one PMN substance will provide scientifically valid and useful information on the other PMN substance(s) covered by the Consent Order.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

[redacted]

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Consent Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substances [redacted] (P-16-356) and [redacted] (P-16-357)("the PMN substances") 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 PMN substances 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 PMN substances for use in the United States, the requirements of this Consent Order do not apply to manufacture, processing or distribution in commerce of the PMN substances solely for export in accordance with TSCA §§12(a) and 12(b), 40 C.F.R. § 720.3(s) and 40 C.F.R. pt. 707. However, once the Company begins to manufacture, process, or distribute in commerce the PMN substances for use in the United States, no further activity by the Company involving the PMN substances is exempt as "solely for export" even if some amount of the PMN substances is later exported. At that point, the requirements of this Consent Order apply to all activities associated with the PMN substances while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substances that are destined for export are subject to terms of the Consent Order, and count towards any production limit test triggers in the Testing section of this 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 PMN substances 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. § 720.36. The requirements of this Consent Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances when manufactured solely for non-commercial research and development as defined at 40 C.F.R. § 720.30(i).

(3) Byproducts. The requirements of this Consent Order do not apply to the PMN substances when produced, without separate commercial intent, only as a "byproduct" as defined at 40 C.F.R. § 720.3(d) and in compliance with 40 C.F.R. § 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Consent Order do not apply to the PMN substances when manufactured, pursuant to any of the exemptions in 40 C.F.R. § 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(5) Imported Articles. The requirements of this Consent Order do not apply to the PMN substances when imported as part of an "article" as defined at 40 C.F.R. § 720.3(c) and in compliance with 40 C.F.R. § 720.22(b)(1).

(6) Completely Reacted (Cured). The requirements of this Consent Order do not apply to quantities of the PMN substances after they have been completely reacted.

(c) Automatic Sunset. If the Company has obtained for the PMN substances 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, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

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

PROHIBITION

The Company is prohibited from manufacturing (which under TSCA includes importing), processing, distributing in commerce, using, or disposing of the PMN substances 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 PMN substances, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Consent Order.

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substances which reasonably support the conclusion that the PMN substances present a substantial risk of injury to health or the environment and which are required to be reported under § 8(e) of TSCA must reference the appropriate PMN identification numbers for the PMN substances and contain a statement that the PMN substances are 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 PMN identification number for each PMN substance and a statement that the PMN 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 PMN, using the procedures set out in 40 C.F.R. § 720.40.

(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 PMN, using the procedures set out in 40 C.F.R. § 720.40. 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 PMN substances 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 PMN substances to mitigate exposures to or to better characterize the risks presented by the PMN substances. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, processing, distribution, use and disposal of the PMN substances, 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 PMN substances 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 PMN substances.

PROTECTION IN THE WORKPLACE

(a) Establishment of Program. During manufacturing, processing, and use of the PMN substances at any site controlled by the Company (including any associated packaging and storage and during any cleaning or maintenance of equipment associated with the PMN substances), the Company must establish a program 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 PMN substances through direct handling of the PMN substances or through contact with equipment on which the PMN substances may exist. 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 PMN substances 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) Specific Dermal Protective Equipment. The dermal protective equipment required by subparagraph (a)(1) of this section must include, but is not limited to, the following items:

(i) Gloves.

(3) 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 must 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 PMN substances.

(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 PMN substances alone and in likely combination with other chemical substances in the work area.

(b) De Minimis Concentrations. The requirements of this section do not apply to quantities of the PMN substances 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 PMN substances are identified as potential carcinogens 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 PMN substances 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.

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Consent Order, the Company becomes aware that the PMN substances may present a risk of injury to health and the environment (or is so notified by EPA), the Company must incorporate this new information, and

any information on methods for protecting against such risk, into an SDS or MSDS, as described in 40 C.F.R. § 721.72(c), within 90 days from the time the Company becomes aware of the new information. If the PMN substances are not being manufactured (which includes import), processed, or used in the Company's workplace, the Company must add the new information to an SDS or MSDS before the PMN substances are reintroduced into the workplace.

(b) The Company must ensure that persons who will receive the PMN substances from the Company, or who have received the PMN substances from the Company within 5 years from the date the Company becomes aware of the new information described in paragraph (a) of this section, are provided an SDS or MSDS containing the information required under paragraph (a) within 90 days from the time the Company becomes aware of the new information.

HAZARD COMMUNICATION PROGRAM

(a) Written Hazard Communication Program. The Company must develop and implement a written hazard communication program for the PMN substances 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 PMN substances are known to be present and must use the identity provided on the SDS or MSDS for the PMN substances 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 PMN substances (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substances contained in unlabeled pipes in their work area.

(3) The methods the Company will use to inform contractors of the presence of the PMN substances 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 PMN substances while in the Company's workplace.

(b) Labeling.

(1) The Company must ensure that each container of the PMN substances in the workplace are 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), if any, identified either in paragraph (f) of this section or by the Company, for the PMN substances.

(B) The identity by which the PMN substances may be commonly recognized.

(C) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified either in paragraph (f) of this section, or by the Company, for the PMN substances.

(D) A statement of exposure and precautionary measure(s), if any, identified either in paragraph (f) of this section, or by the Company, for the PMN substances.

(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 PMN substances are 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 PMN substances 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 PMN substances leaving its workplace for distribution in commerce are 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 PMN substances 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 PMN 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 PMN substances 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 PMN substances are 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 PMN substances are 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 PMN substances.

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

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

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

(iii) The physical hazards of the PMN substances 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 PMN substances known to the Company.

(vi) The primary routes of exposure to the PMN substances.

(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.

(viii) Any generally applicable precautions for safe handling and use of the PMN substances 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 PMN substances 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 PMN substances 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 PMN substances 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 PMN substances are 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 PMN substance is reintroduced into the workplace.

(6) The Company must ensure that persons receiving the PMN substances 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 PMN substances 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 PMN substances. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substances and whenever the PMN substances are 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 PMN substances are 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 by paragraph (c) of this section.

(2) The training provided to employees must include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substances 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 PMN substances when being released).

(ii) The potential human health and environmental hazards of the PMN substances as specified in paragraph (f) of this section.

(iii) The measures employees can take to protect themselves and the environment from the PMN substances, including specific procedures the Company has implemented to protect employees and the environment from exposure to the PMN substances, 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 section, 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 Hazard Communication section do not apply to quantities of the PMN substances 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 PMN substances are identified as potential carcinogens 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 PMN substances 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) skin irritation.

(ii) respiratory complications.

(iii) neurotoxicity

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

(i) avoid skin contact.

(ii) avoid ingestion.

(iii) use skin protection.

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

(i) toxic to fish.

(ii) toxic to aquatic organisms.

(4) 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."

(5) 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.

MANUFACTURING

(a)(1) Prohibition. The Company must not cause, encourage, or suggest the manufacture (which includes import) of the PMN substances by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) will expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substances 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, subparagraph (a)(1) will not expire

until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. If and when EPA promulgates a final SNUR for the PMN substances and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company must notify each person whom it causes, encourages or suggests to manufacture the PMN substances of the existence of the SNUR.

(b) The Company must not manufacture the PMN substances:

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

(2) with any modifications if they result in generation of vapor, mist or aerosol exposure for workers; and

(3) other than as a [redacted]

PROCESSING

(a) The Company must not process the PMN substances:

(1) with any modifications that results in the generation of vapor, mist or aerosol exposure for workers.

(2) must provide personal protective equipment to its workers to prevent dermal exposure; and,

(3) other than as a [redacted]

USE

(a) The Company must not use the PMN substances:

(1) with any modifications that results in the generation of vapor, mist or aerosol exposure for workers.

(2) must provide personal protective equipment to its workers to prevent dermal exposure; and,

(3) other than as a [redacted]

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 PMN substances that, due to the issuance of this Consent Order, the PMN substances are subject to the export notification requirements of TSCA § 12(b) and 40 C.F.R. pt. 707, subpt. D. Such notice must contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identities of the PMN substances, or (B) if the specific chemical identities are confidential, the generic chemical identities.

(b) Distribution Requirements. Except after the PMN has been completely reacted and except as provided in paragraph (c) the Company is permitted to distribute the PMN substances 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 PMN substances that, due to the issuance of this Consent Order under § 5(e) of TSCA, the PMN substances are subject to the

export notification requirements of TSCA § 12(b) and 40 C.F.R. pt. 707, subpt. D. Such notice must contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN numbers, and (2) either (A) the specific chemical identities of the PMN substances, or (B) if the specific chemical identities are confidential, the generic chemical identities.

(2) Not further distribute the PMN substances to any other person, other than for disposal, until after the PMN substances have been completely reacted (cured).

(3) Comply with the same requirements and restrictions, if any, required of the Company in the Protection in the Workplace section.

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

(5) Not process or use the PMN substances:

(i) with any modifications that results in the generation of vapor, mist or aerosol exposure for workers;

(ii) must provide personal protective equipment to its workers to prevent dermal exposure; and,

(iii) other than as a [redacted]

(c) Temporary Transport and Storage. Notwithstanding paragraph (b), the Company may distribute the PMN substances outside the Company for temporary transport and storage in sealed containers provided the following three conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the PMN substances may be distributed only to the Company or a person who has given the Company the written agreement required by paragraph (b).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substances may occur only while the PMN substances are in the possession and control of the Company or a person who has given the Company the written agreement required by paragraph (b).

(3) The sealed containers must be labeled in accordance with paragraph (b)(2) of the Hazard Communication Program section of this Consent Order.

(d) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substances, the Company obtains knowledge that a recipient of the PMN substances 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 PMN substances (as defined in 40 C.F.R. pt. 721, subpt. E) without submitting a significant new use notice to EPA, the Company must cease supplying the PMN substances 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 PMN substances 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 PMN substances 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 PMN substances without submitting a significant new use notice to EPA, the Company must cease supplying the PMN substances to that recipient, must notify EPA of the failure to comply, and is permitted to resume supplying the PMN substances to that recipient only upon written notification from the Agency.

(e) 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 SNUR for the PMN substances 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 (b) 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 been resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final SNUR for the PMN substances 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 PMN substances of the existence of the 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 PMN substances. Such notice must also reference the publication of the SNUR for the PMN substances in either the Federal Register or the Code of Federal Regulations.

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 PMN substances 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 PMN substances 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 PMN substances 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. § 720.78(b). For any amounts or batches of the PMN substances 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 PMN substances 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 PMN substances, the date of each sale or transfer, and the quantity of the PMN substances 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 PMN substances;

(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, Processing, Use, and Distribution sections

of this Consent Order, including distributees' written agreement to comply with the Distribution section of this Consent Order;

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

(13) The Company must keep a copy of this Consent Order at each of its sites where the PMN substances are 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. pt. 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 and 40 C.F.R. § 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substances. 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 PMN substances will be in production within the subsequent 12 months;

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

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

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

(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. pt. 2, subpt. 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 PMN. 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 PMN substances, including the right to manufacture the PMN substances, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substances from the Company pursuant to 40 C.F.R. § 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with § 5(a)(1)(B) of TSCA and 40 C.F.R. pt. 720 before commencing manufacture (which includes import) of the PMN substances.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest must comply with the terms of this Consent Order and will not be required to submit a new PMN 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 PMN substances, 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 PMN substances, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substances. 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 PMN substances, including the right to manufacture the PMN substances, 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, by registered mail, submit the fully executed Notice of Transfer document to EPA at:

Postal Mail Address

U.S. Environmental Protection Agency

New Chemicals Management Branch (7405M)

1200 Pennsylvania Avenue, N.W.

Washington, D.C. 20460

Alternatively, the document may be submitted by courier:

U.S. Environmental Protection Agency

New Chemicals Management Branch (7405M)

1201 Constitution Avenue, N.W.

Washington, D.C. 20004

(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 PMN substances are 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 PMN substances 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 PMN substances pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substances manufactured by the Company up to the date of transfer will count towards the test trigger applicable to the Successor in Interest.

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 PMN substances, 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 PMN substances 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 PMN substances.

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 PMN 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.

2 Nov 2017
Date

Jeffery T. Morris, Director
Office of Pollution Prevention and Toxics

[redacted]

22 Feb 18
Date

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 PMN 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.

"PMN substances" means the chemical substances described in the Premanufacture notices 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.

"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. pt. 792 without prior or subsequent Agency review that prevents a reasoned evaluation of the health or environmental effects of the PMN 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 PMN 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 PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN 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 PMN 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) PMN 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 ("PMN") 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 PMN 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. pt. 2, for the PMN 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 PMN.

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

(continued)

Company (Transferor)	PMN 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