JW 6/22/17
MAM 7/10/17

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 Number:
	)	
	)	
	)	
	)	
	)	
[redacted]	)	P-16-0595
	)	
	)	
	)	
	)	
	)	SANITIZED

Consent Order and Determinations Supporting Consent Order

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PREAMBLE

I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notice ("PMN") P-16-0595 for the chemical substance [redacted] ("the PMN substance") submitted by [redacted] ("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMN to EPA pursuant to § 5(a)(1)(B) of TSCA and 40 CFR part 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, and to specific enforcement and seizure pursuant to § 17. 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 ORDER

This Consent Order requires the Company to:

(a) Not use other than as stated in the PMN as a [redacted]

(b) Import only in containers as stated in the PMN [redacted]

[redacted]

(c) Not manufacture (excluding import) the PMN substance domestically;

(d) Manufacture (which includes import) PMN substance such that the proportion of the [redacted]

(e) not release the PMN substance into the waters of the United States; and

(f) maintain certain records.

III. CONTENTS OF PMN

By signing this 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 Order):

Company Information, Molecular Weight, Chemical Identity, Trade Name, Production Volume, and Use,

Chemical Identity:
Specific: [redacted]

Generic:
Substituted-(hydroxyalkyl)-alkyl-alkanoic acid, hydroxy-(substitutedalkyl)-alkyl-, polymer with alpha-hydro-omega-hydroxypoly[oxy(alkylethanediyl)]
and isocyanato-(isocyanatoalkyl)-multialkylcycloalkane, salt, alkanol-blocked, compds.

Use:

Specific: [redacted]

Generic: Polymer

Maximum 12-Month Production Volume: [redacted]

Test Data Submitted with PMN: Physical and Chemical Properties and Ames Test Report

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 substance, based on the information currently available to the Agency.

Human Health Effects Summary:

Absorption: Absorption is nil through the skin for the polymer and the amine counter ion, poor through the lungs and GI tract for the low molecular weight fraction of the polymer [redacted] and good through the lungs and GI tract for the [redacted] based on physical and chemical properties.

Toxicological Endpoints of Concern: Irritation to skin, eyes, and lungs, kidney and developmental effects.

Basis: Based on [redacted] present in the structure.

Environmental Effects Summary:

Risk to the environment is based on SAR chemical class predictions for polyanionic polymers. If a low molecular weight polymer is produced under the same CAS RN, with a different average molecular weight, proportion of repeating units, and/or its percentage, the determination may be different. Specifically, [redacted] or the molecular weight is within a range that allows for solubility or sorption, then hazard concerns may result. See https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemical-categories-used-review-new

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 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 PMN substance and that the PMN substance may cause irritation, kidney and developmental effects and, if made differently, environmental effects. 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 substance may present an unreasonable risk of injury to health and the environment and that the limitations imposed by this order are necessary to protect against such risk.

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Pended Testing. The following additional information would be required to evaluate the following effects which may be caused by the PMN substance:

Human Health Testing

- Acute Dermal Irritation Test (OPPTS Test Guideline 870.2500); and,
- Acute Eye Irritation Test (OPPTS Test Guideline 870.2400).

Ecotoxicity Testing

Tier one will be testing on physical/chemical properties:

- Compositional/component analysis with certificate of analysis;
- Water solubility – Harmonized Test Guideline 830.7840 or 830.7860; and
- Octanol/water partition coefficient (Kow) – Harmonized Test Guideline 803.7550 or 830.7560 or 830.7570; or OECD 123, Partition Coefficient (1-Octanol /Water): Slow-Stirring Method.

Tier two will be the acute base set:

- Fish Acute Toxicity Test, freshwater and marine (OPPTS Test Guideline 850.1075);
- Aquatic Invertebrate Acute Toxicity Test (OPPTS Test Guideline 850.1010); and
- Algal Toxicity (OCSPP Test Guideline 850.4500).

Tier three will be the chronic base set:

- Fish Early-Life Stage Toxicity Test (OPPTS Test Guideline 850.1400) and
- Daphnid Chronic Toxicity Test (OPPTS Test Guideline 850.1300).

The Order does not require submission of the above pended testing at any specified time or production volume. However, the Order's restrictions on manufacture and use of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

NOTE: Any request by EPA for the triggered and pended testing described in this 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 substance. 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.

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

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substance P-16-0595 [redacted] ("the PMN 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 PMN substance is exempt from the requirements of this 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 Order.

(1) Export. Until the Company begins commercial manufacture of the PMN substance for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substance solely for export in accordance with TSCA §§12(a) and 12(b), 40 CFR 720.3(s) and 40 CFR part 707. However, once the Company begins to

manufacture, process, or distribute in commerce the PMN substance for use in the United States, no further activity by the Company involving the PMN substance is exempt as "solely for export" even if some amount of the PMN substance is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substance that are destined for export are subject to terms of the Order, and count towards any production limit test triggers in the Testing section of this Order.

(2) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance when manufactured solely for non-commercial research and development per TSCA §5(i) and 40 CFR 720.30(i).

(3) Byproducts. The requirements of this Order do not apply to the PMN substance when it is produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substance when it is manufactured, pursuant to any of the exemptions in 40 CFR 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 Order do not apply to the PMN substance when it is imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(c) Automatic Sunset. If the Company has obtained for the PMN substance a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 CFR 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, USE, AND DISPOSAL 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 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 substance, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substance which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or the environment and which is required to be reported under TSCA section 8(e) must reference the appropriate PMN identification number for this substance and contain a statement that the

substance is subject to this Consent Order. Additional information regarding section 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 Order, or within 15 days after the effective date of this 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 substance and a statement that the 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 CFR 720.40.

(c) Good Laboratory Practice Standards and Test Protocols. Each study performed to address the risks identified in this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR 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 CFR 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 Order, the PMN 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 PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, processing, distribution, use and disposal of the PMN 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 PMN substance in accordance with the terms of this 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 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 Part VI. of this Consent Order.

MANUFACTURING

(a)(1) Prohibition. The Company must not cause, encourage, or suggest the manufacture (which includes import) of the PMN substance 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 substance under section 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. When EPA promulgates a final SNUR for the PMN substance 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 substance of the existence of the SNUR.

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

(1) In the United States and must only import the PMN substance in [redacted]; and

(2) Such that the portion of [redacted].

USE

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

(1) Other than as described in the PMN as [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 substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart 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 identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(b) Distribution Requirements. Except for distribution of [redacted] to distributors, dealers, resellers, customers or end users who will conduct no further processing of the PMN substance, the Company is permitted to distribute the PMN 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 PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CPR Part 707 Subpart 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 identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(2) Comply with the same environmental release restrictions, if any, required of the Company in the Disposal and Release to Water sections of this Order.

(3) Not use the PMN substance other than as [redacted]

(c) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substance, the Company obtains knowledge that a recipient of the 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 (d)(1), has engaged in a significant new use of the PMN substance (as defined in 40 CPR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Company must cease supplying the 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 PMN 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 PMN 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 (c)(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 substance without submitting a significant new use notice to EPA, the Company must cease supplying the PMN substance to that recipient, must notify EPA of the failure to comply, and is permitted to resume supplying the PMN substance to that recipient only upon written notification from the Agency.

(d) Sunset Following SNUR and Notification of SNUR.

(1) Paragraph (b) of this Distribution section will expire 75 days after promulgation of a final SNUR for the PMN substance under section 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, paragraph (b) 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 substance and paragraph (b) of this Distribution section expires in accordance with subparagraph (d)(1), the Company must notify each person to whom it distributes the PMN substance 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 substance. Such notice must also reference the publication of the SNUR for this PMN 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 PMN substance, or any waste stream from manufacturing processing or use containing the PMN substance into the waters of the United States.

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 section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this 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 substance eligible for the export only exemption in Section I, Paragraph (b)(1) of this 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 sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substance eligible for the research and development exemption in Section I, Paragraph (b)(2) of this 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 CFR 720.78(b). For any

amounts or batches of the PMN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this 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 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 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 compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, Use, and Distribution sections of this Order;

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

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

(8) The Company must keep a copy of this Order at each of its sites where the PMN 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 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this 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 section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN 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 PMN substance will be in production within the subsequent 12 months;

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

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

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

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

(6) Any other information reasonably related to determining compliance with this 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 CFR part 2. 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.

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 Order may be transferred when the Company transfers its interests in the PMN substance, including the right to manufacture the PMN substance, 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 substance from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with Section 5(a)(1)(B) of TSCA and 40 CFR part 720 before commencing manufacture (which includes import) of the PMN substance.

(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 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 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 substance, 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 substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3) and 40 CFR 720.3(z).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substance, including the right to manufacture the PMN substance, 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 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 substance is manufactured. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN substance under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company will be liable for compliance with the requirements of this 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 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 substance pursuant to the terms of this Consent Order.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA 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 substance, to modify or revoke substantive provisions of this 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 substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke the substantive provisions of this 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 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 substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this 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 Order as issued.

VII. EFFECT OF CONSENT ORDER

(a) Waiver. By consenting to the entry of this Order, the Company waives its rights to receive service of this Order no later than 45 days before the end of the applicable review period pursuant to section 5(e)(1)(B) of TSCA and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this 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.

6/5/17
Date

Maria J. Doa, Ph.D., Director
Chemical Control Division
Office of Pollution Prevention and Toxics

6/20/17
Date

[redacted]

ATTACHMENT A

DEFINITIONS

[Note: The attached 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 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 Part 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 substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this 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 CFR Part 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 CFR 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 CFR 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 CFR part 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