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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:
	)	
	)	
	)	CONTAINS NO CBI
	)	
	)	
Qualice, LLC	)	P-14-0683 and P-14-0684
	)	
	)	
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	)	

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 notices ("PMNs") P-14-0683 and P-14-0684 for the chemical substances Tetradecane, chloro derivatives (CASRN 198840-65-2) (P-14-0683) and Alkanes, C14-16, chloro, CAS 1372804-76-6 (P-14-0684) ("the PMN substances") submitted by Qualice, LLC ("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMNs 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) submit to EPA certain toxicity testing by a certain time limit;

(b) not use the PMN substances for other than as a flame retardant and plasticizer in PVC and polymers; a flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings;

an additive in lubricants including metalworking fluids; a flame retardant and plasticizer in rubber; and a flame retardant and waterproofer in textiles; and,

(c) 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): None

Chemical Identity:

Tetradecane, chloro derivatives (CASRN 198840-65-2) (P-14-0683)

Alkanes, C14-16, chloro (CAS 1372804-76-6) (P-14-0684)

Use: a flame retardant and plasticizer in PVC and polymers; a flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; an additive in lubricants including metalworking fluids; a flame retardant and plasticizer in rubber; and a flame retardant and waterproofer in textiles;

Maximum 12-Month Production Volume: 15,000,000 kg, each PMN substance

Test Data Submitted with PMN: None

IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

EPA's assessment of the potential human health and environmental toxicity as well as potential exposure and risk is described in detail in the "TSCA New Chemicals Program Standard Review Risk Assessment on Medium-Chain Chlorinated Paraffins (PMNs P-14-0683, P-14-0684)"

(Attachment C to the Consent Order). As discussed in the risk assessment, EPA evaluated available data on Medium-Chain Chlorinated Paraffins (MCCPs). That assessment is briefly summarized here.

Persistence and Bioaccumulation Concerns:

EPA has concluded that the PMN substances may be very persistent and very bioaccumulative according to the criteria described in the New Chemicals Program's PBT category (64 FR 60194, November 4, 1999)(FRL-6097-7). At least some congener groups present in MCCP products may be persistent to very persistent, with estimated half-lives in air exceeding 2 days and estimated half-lives in water or sediments exceeding 2 months. At least some congener groups present in MCCP products may be bioaccumulative to very bioaccumulative based on multiple lines of evidence, including: Log Kow values, modeled BCFs, laboratory-measured BCFs, field-measured BAFs, field-measured BMFs, laboratory-measured biota-sediment bioaccumulation factors (BSAFs) and the presence of MCCPs in human and wildlife biota.

Human Health Effects Summary:

Absorption: Based upon low vapor pressure and low water solubility, absorption of MCCPs following inhalation or dermal exposure is expected to be limited. Moderate absorption and metabolism following oral exposure in animals has been observed for some MCCPs, generally those with a shorter carbon chain length and lesser degree of chlorination. EPA expects similar absorption and metabolism for the PMN substances.

Toxicological Endpoints of Concern: Systemic toxicity.

Basis: From the data available on MCCPs, a LOAEL of 625 mg/kg-bw/day based on histopathological changes in the kidneys of female rats is identified in a 90-day toxicity study, and a NOAEL of 23 mg/kg-bw/day based on increased kidney weight at 222 mg/kg-bw/day is identified from another 90-day study in rats. In EPA's risk assessment, the lowest NOAEL (90-day value of 23 mg/kg-bw/d from the rat study described above) was used to assess occupational and non-occupational (*i.e.*, general population) risks of MCCPs.

Environmental Effects Summary:

Ecotoxicity studies for MCCPs have been conducted in fish, aquatic invertebrates and plants, sediment and soil invertebrates, and terrestrial plants and invertebrates. Although no avian reproduction studies were available on MCCPs, a high quality study available on a short-chain chlorinated paraffin (SCCP) product (C_{10-12}, 58 wt% Cl) with similar physicochemical properties to MCCPs was used for informing EPA/OPPT's hazard evaluation. Based on these studies, EPA developed the following environmental concentrations of concern (COCs) with respect to the PMN substances:

COCs for Environmental Toxicity of MCCPs.

Compartment	Test organism	Endpoint	Value	Assessment factor	Concentration of Concern (COC)
Surface water	Water flea	EC_{50}	5.9 µg/L	5	1.2 µg/L
		21-day MATC	13 µg/L	10	1.3 µg/L
Sediment	Amphipod	MATC	187 mg/kg dw	10	18.7 mg/kg dry wt. sediment
Terrestrial	Earthworm	28-day MATC	149 mg/kg dw	10	14.9 mg/kg dry wt. soil
	Mallard duck	22-week NOEC	168 mg/kg diet	10	16.8 mg/kg diet

Exposure and Risk:

Based on its assessment of the available hazard and exposure information on P-14-0683/0684, EPA/OPPT concludes the following pertaining to the potential manufacturing, processing and use of these PMN substances:

1. Occupational Exposures: given the assumptions, data and scenarios for the PMN substances evaluated in this assessment, there were no unreasonable risks found to workers from either inhalation or dermal exposures during manufacturing, processing or use.

2. General Population Exposures (from environmental releases): given the assumptions, data and scenarios for the PMN substances evaluated in this assessment, there were no unreasonable risks found to humans from environmental releases via exposure to drinking water or fish ingestion. Similarly, there were no unreasonable risks found to humans from environmental releases via inhalation exposures from emissions from facilities stacks or fugitive emissions from the manufacturing and processing facilities.

3. Environmental Assessment:

   a. Using the conventional EPA PMN method of estimating water concentrations, the PMN substances are expected to result in releases to surface water at concentrations that **may present an unreasonable risk following acute and chronic exposures to aquatic organisms.** Use of additional information submitted in response to comments on a previous draft did result in decreases of estimated risk values for some scenarios, but the unreasonable risk finding still stands.

b. Using available measured concentrations of MCCP congener groups in the environment as supporting information, the PMN substances:

   i. Are expected to partition to sediment and may partition to soil through land application of biosolids and,

   ii. May be released to the environment at water concentrations that **may present n unreasonable risk following acute and chronic exposures to aquatic organisms.**

   iii. May be released to the environment resulting in sediment concentrations that **may present an unreasonable risk following chronic exposures to sediment organisms.**

4. PBT Assessment: The PMN substances **may be very persistent and very bioaccumulative.**

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 environmental exposure to the PMN substances and that the PMN substances may be very persistent and very bioaccumulative, and may present an unreasonable risk to aquatic and sediment organisms. 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 or the environment and that the limitations imposed by this order are necessary to protect against such risk.

(b) EPA has determined that because MCCPs similar to the PMN substances have been manufactured, processed and used for the uses described in the PMN for more than 40 years, manufacture, processing, distribution in commerce, use and disposal of the PMN substances in accordance with the provisions of this order do not create an unreasonable risk of injury to health or the environment.

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Triggered Testing. The Order specifies conditions under which the Company is required to submit the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.

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 substances Tetradecane, chloro derivatives (CASRN 198840-65-2) (P-14-0683) and Alkanes, C14-16, chloro (CAS 1372804-76-6) (P-14-0684) ("the PMN substances") in the United States by Qualice, LLC ("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 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 substances for use in the United States, the requirements of this 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 CFR 720.3(s) and 40 CFR part 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 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 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 substances 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 substances 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 substances when 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 substances when manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substances, mixture, or article of which it is a part.

(5) Imported Articles. The requirements of this Order do not apply to the PMN substances when 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 substances 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

Beginning five years following the date of submission of a Notice of Commencement of Manufacture ("NOC"), 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, unless the Company conducts the following studies on the PMN substances and submits all final reports and underlying data in accordance with the conditions specified in this Testing section. This information is necessary for a reasoned evaluation of the environmental effects of the substances. After that period, the activities described in this paragraph may not resume until EPA has completed review of, and taken any regulatory action deemed appropriate by EPA 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 substances which reasonably supports the conclusion that the PMN substances present 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 the 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) Triggered Testing Requirements.

(1) Synthesis and Characterization of Substances to be Tested

The Company must synthesize ~~or purchase~~ and characterize the following representative congener groups (hereinafter referred to collectively as the "test substances"):

- Chlorinated linear C_{14} paraffin fractions to represent the 30- and 56-wt% Cl.
- One chlorinated linear C_{16} paraffin fraction to represent the 56-wt% Cl.

The characterization of the test substances must be performed using appropriate analytical methods (*e.g.*, GC/MS, HPLC/MS) that provide the carbon chain length and the wt% Cl.[1] The Company must provide EPA with a certificate of analysis and all "raw data"[2] from the analyses of the test substances.

(2) Degradation Testing: Transformation Studies

C_{14} and C_{16} with 56 wt%

OECD Guideline 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems with analytical procedures capable of measuring the test substances and their degradation products over time.

(3) Toxicity Testing

Testing must begin with the C_{14} 30 wt-% Cl congener.

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[1] See, *e.g.*, Jana Hüttig and Michael Oehme (2006) *Congener group patterns of chloroparaffins in marine sediments obtained by chloride attachment chemical ionization and electron capture negative ionization*, CHEMOSPHERE, Vol. 64, pp. 1573-1581, at p. 1576 (Figure 1).

[2] Note, the terms "raw data" as used herein are the same as defined under 40 CFR Part 792 – Good Laboratory Practice Standards, §792.3 Definitions.

C_{14} with 30 wt%

1. OECD Guideline 225: Sediment-Water *Lumbriculus* Toxicity Test Using Spiked Sediment.
2. OECD Guideline 211 (OPPTS 850.1300): *Daphnia magna* Reproduction Test.

If adverse effects are observed in study 1 at concentrations below 1,000 mg/kg (dry weight) or in study 2 at concentrations up to the solubility limit, then the Company must perform the following toxicity tests.

C_{16} with 56 wt%

1. OECD Guideline 225: Sediment-Water *Lumbriculus* Toxicity Test Using Spiked Sediment.
2. OECD Guideline 211 (OPPTS 850.1300): *Daphnia magna* Reproduction Test.

(4) Bioaccumulation Testing

If any adverse effects are seen in any of the toxicity testing at the previously stated cutoff levels, then the Company must perform the following bioaccumulation testing.

C_{16} with 56 wt% Cl

1. OECD Guideline 315: Bioaccumulation in Sediment-dwelling Benthic Oligochaetes with analytical procedures capable of measuring the test substances and their degradation products; and
2. OECD Guideline 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure. The dietary exposure protocol must be used with analytical procedures capable of measuring the test substances and their degradation products.

If, based on the results of testing conducted, EPA determines that the PMN substances or any degradation products may present unreasonable risks to human health or the environment, EPA may, in accordance with paragraph (j) of this Testing section, require additional characterization or restrictions on the manufacture (which includes import), 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 or their degradation products.

Until the Company submits all final reports and underlying data, the Company must submit to EPA a letter reporting the cumulative manufacture (which includes import) volume of the PMN substances every year. The annual letter report must be submitted by January 31 of the year subsequent to the reporting year. This annual letter report must be submitted as a support document for the PMN, using the procedures set out in 40 CFR 720.40.

(e) Test Reports. The Company must: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study, if requested by EPA; and (3) submit the final report of each study (with an additional sanitized copy, if confidential business information is involved) and all underlying data ("the report and data") to EPA prior to exceeding the applicable production limit. The final report and data must be submitted as a support document for the PMN, using the procedures set out in 40 CFR 720.40. The final report must contain the contents specified in 40 CFR 792.185. Underlying data must be submitted to EPA in accordance with the applicable "Reporting," "Data and Reporting," and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs will be interpreted to

mean "must" to make clear that performing the applicable procedures and submitting the applicable information are mandatory. EPA will require the submission of raw data such as slides and laboratory notebooks only if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture the PMN substances beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e) (except that the study may be submitted after reaching the applicable production limit). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substances, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture of the PMN substances beyond the applicable production limit.

(2) The Company may continue to manufacture the PMN substances beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) If there is sufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may reconduct the study. If there is insufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may exceed the production limit, but must otherwise comply with paragraphs (b), (c), and (e), and must submit the report and data to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data.

(1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture of the PMN substances beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the

Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture the PMN substances beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e), if there is sufficient time to conduct or reconduct the study and submit the report and data to EPA before exceeding the production limit specified in paragraph (d). If there is insufficient time for the Company to comply with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may exceed the production limit, but must otherwise comply with paragraphs (b), (c), and (e), and must submit the report and data to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture beyond the applicable production limit.

(j) 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 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 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.

(k) 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.

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Order, the Company becomes aware that the PMN substances may present a risk of injury to 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 CFR section 721.72(c), within 90 days from 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.

MANUFACTURING

(a) Manufacturing by Others.

(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 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 substances and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company must notify each person whom it [redacted]ges or suggests to manufacture the PMN substances of the existence of the SNUR.

PROCESSING/USE

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

(1) Other than as: a flame retardant and plasticizer in PVC and polymers; a flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; an additive in lubricants including metalworking fluids; a flame retardant and plasticizer in rubber; and a flame retardant and waterproofer in textiles.

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 under section 5(e) of TSCA, the PMN substances are 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. 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 section 5(e) of TSCA, the PMN substances are 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.

(c) 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 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, 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 section 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 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 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 substances 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 substances 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 substances and the corresponding dates of manufacture;

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons 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 substances sold or transferred on such date;

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

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

(6) The Company must keep a copy of this 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 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 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 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 handled in accordance with §14 of TSCA, 40 CFR part 720, subpart E, and 40 CFR part 2, subpart B. In addition, 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 substantiated as required by TSCA Section 14(c)(1)(C)(3). See https://www.epa.gov/tsca-cbi/substantiating-cbi-claims-under-tsca-time-initial-submission for EPA guidance on how to comply with Section 14(c)(1)(C)(3).

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 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 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 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 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 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 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 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 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 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 substances 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 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 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 substances, 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 substances 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 substances.

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.

VI. EFFECT OF CONSENT ORDER

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.

5-8-17
Date

Lynn Vendinello
Lynn Vendinello, Acting Director
Chemical Control Division
Office of Pollution Prevention and Toxics

5/16/17
Date

Charles M. Davis
Name: Charles M. Davis
Title: President
Company: Qualice, LLC

CONTAINS NO CBI

5/17/17

TSCA CONFIDENTIAL
BUSINESS INFORMATION
DOES NOT CONTAIN NATIONAL
SECURITY INFORMATION (E.O. 12065)

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. CBI claims must be substantiated as required by TSCA Section 14(c)(1)(C)(3). See https://www.epa.gov/tsca-cbi/substantiating-cbi-claims-under-tsca-time-initial-submission for EPA guidance on how to comply with Section 14(c)(1)(C)(3).

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

ATTACHMENT C

TSCA New Chemicals Program Standard Review Risk Assessment on Medium-Chain Chlorinated Paraffins (PMNs P-14-0683, P-14-0684)