

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:

[ ]

P-08-0177

**EPA SANITIZED**

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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 notice (“PMN”) P-08-0177 for the chemical substance multiwalled carbon nano tubes, (“MWCNT” or the “PMN substance”) submitted by [ ], (“the Company”), to take effect upon expiration of the PMN review period. The Company submitted the PMN to EPA pursuant to section 5(a)(1) 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 § 5 or any order issued under § 5. 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**

The Consent Order for this PMN substance requires the Company to:

- (1) Deliver to EPA a 1 gram sample of the PMN substance along with a copy of MSDS;
- (2) Submit to EPA the results of a 90-day inhalation toxicity study in rats with a post exposure observation period of up to 3 months, including bronchoalveolar lavage fluid (“BALF”) analysis (OPPTS 870.3465 or OECD 413) at least 14 weeks before either (a) manufacturing or importing a total of [ ] kg of the PMN substance, or (b) [ ] years [ ] months

after commencing non-exempt commercial manufacture of the PMN substance, whichever comes first. The production/time limit shall be calculated from a date 2 years after signing this Consent Order by the Company,

- (3) Within 6 months of commencing non-exempt commercial manufacture of the PMN substance, submit certain material characterization data;
- (4) Use gloves impervious to nanoscale particles and chemical protective clothing;
- (5) Use a NIOSH-approved full-face respirator with an N -100 cartridge while exposed by inhalation in the work area;
- (6) Use the PMN substance only as a [            ];
- (7) distribute the PMN substance only to a person who agrees to follow the same restrictions (except the testing requirements); and
- (8) maintain certain records.

### **III. CONTENTS OF PMN**

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

name of the technical contact, the name of the company, production volume, uses

Chemical Identity: multi-walled carbon nanotubes

Use:

Specific : [     ]

Generic: property modifier in electronic applications, contained use, property modifier in polymer composites, contained use.

Maximum 12-Month Production Volume: [   ] kg

Test Data Submitted with PMN: none

#### **IV. EPA'S ASSESSMENT OF RISK**

The following are EPA's predictions regarding the probable 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 of the PMN chemical is expected to be poor via all routes of exposure.

**Toxicological Endpoints:** There is a concern for health effects based on analogy to respirable, poorly soluble particulates and other carbon nanotubes and for lung irritation based on particle size.

**Basis:** chemical category, see [www.epa.gov/oppt/newchemicals/chemcat.htm](http://www.epa.gov/oppt/newchemicals/chemcat.htm)

Environmental Effects Summary: No significant effects expected.

##### Exposure and Environmental Release Summary:

Scenario	No. of Sites	No. of Workers	Inhal (mg/d)	Dermal (mg/d)	Release to water (kg/y)
Use 1	[ ]	[ ] [ ]	0.02	1600 3100	13
Use 2	[ ]	[ ] [ ]	0.02	1600 3100	13

During Use 1 and Use 2, [ ] workers are expected to be exposed by both inhalation and dermal

routes, and [ ] workers are expected to be exposed via the dermal route only.

Risk to Workers: health risk to workers exposed to the PMN chemical via the inhalation route and via the dermal route.

Risk to General Public: potential risk to the general population from water, landfill and/or incineration releases.

## V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

(A) EPA is unable to determine the potential for human health effects from exposure to the PMN substance. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health effects of the PMN substance.

(B) In light of the potential risk to human health posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health.

## VI. INFORMATION REQUIRED TO EVALUATE HEALTH EFFECTS

Triggered Testing. The Order prohibits the Company from exceeding a specified

production time period or production volume unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section. The Order requires submission of the following triggered testing:

<u>Information</u>	<u>Effects</u>	<u>Guidelines</u>
90-day inhalation toxicity study on rats with a post-exposure observation period of up to 3 months, including bronchoalveolar lavage fluid (“BALF”) analysis.	lung	OPPTS 870.3465 or OECD 413

The Order’s restrictions on manufacture, import, processing, distribution in commerce, use, and disposal 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.

EPA encourages the Company to develop additional health effects testing in coordination with other multi-walled carbon nanotube (MWCNT) manufacturers. This can be done under the in-depth portion of EPA’s Nanoscale Materials Stewardship Program or through independent testing. If, for example, a consortium of companies commit to testing a representative set of MWCNT for subchronic mammalian toxicity, EPA may consider waiving the triggered testing requirement. EPA would be willing to facilitate the process in coordination with other ongoing health effects testing for MWCNT nationally and internationally. EPA would consider accepting the results of such testing in lieu of triggered testing in this order.

## 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, multi-walled carbon nanotubes (MWCNT), P-08-0177 (“the PMN substance”), in the United States by [ ] (“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) Completely Reacted (Cured). The requirements of this Order do not apply to quantities of the PMN substance that have been completely reacted (cured).

(2) 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 (b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture 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 volume test triggers in the Testing section of this Order.

(3) 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.

(4) 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).

(5) 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.

(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, IMPORT, PROCESSING,  
DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL  
PENDING SUBMISSION AND EVALUATION OF INFORMATION**

**PROHIBITION**

The Company is prohibited from manufacturing, 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. Any 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 required to be reported under EPA’s section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978) as amended at 52 Federal Register 20083 (May 29, 1987), shall reference the appropriate PMN identification number for this substance and shall contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found in the reporting guide referenced at 56 Federal

Register 28458 (June 20, 1991).

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Laboratory Data Integrity Branch (2225A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, 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 the substance and a statement that the substance is subject to this Consent Order.

(c) Good Laboratory Practice Standards and Test Protocols. Each study required to be performed pursuant to 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 such study, the Company must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (d) provide general guidance for development of test protocols, but are not themselves acceptable protocols. Approval of the test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements.

(1) 90-day inhalation toxicity study. The Company is prohibited from manufacturing or importing the PMN substance beyond the following aggregate manufacture and import volumes (“the production limits”), unless the Company conducts the following studies on the PMN substance and submits all final reports and underlying data in accordance with the conditions specified in this Testing section. The production/time limit shall be calculated from the date 2 years after signing this Consent Order by the Company.

<u>Production/Time Limit</u>	<u>Study</u>	<u>Guideline</u>
[ ] years [ ] months, or [ ] kg whichever comes first	90-day inhalation toxicity study on rats with a post-exposure observation period of up to 3 months, including bronchoalveolar lavage fluid (BALF) analysis	OPPTS 870.3465 or OECD 413

If an appropriate adaptation of the 90-day inhalation study for the evaluation of MWCNT is not developed within two years of the date the Company signs this Consent Order or if the Company commits to an appropriate program to test representative MWCNTs, e.g., under the in-depth portion of the Nanoscale Materials Stewardship program, the Company may petition EPA, pursuant to Section IV of this Consent Order, to modify the above testing requirement. If a consortium of companies commit to test a representative set of MWCNT for subchronic mammalian toxicity, EPA will consider waiving the above requirement.

(2) Material Characterization. Within 6 months of commencing non-exempt commercial manufacture of the PMN substance, the Company must submit the following material characterization data (including data summaries and procedures) obtained from (1) microscopy analysis (scanning electron microscopy, SEM, or transmission electron microscopy, TEM), and (2) X-Ray analysis (X-ray diffraction, XRD, X-ray fluorescence, XRF, or X-ray spectroscopy, EDX):

- A. type of multi-walled carbon nanotube
  - concentric cylinders or scrolled tubes
  - number of walls/tubes
- B. configuration of nanotube ends (e.g., open, capped)
- C. description of any branching
- D. width/diameter of inner most wall/tube (average and range)
- E. carbon unit cell ring size and connectivity (e.g., typically 6 membered rings but can include other ring sizes)
- F. alignment of nanotube along long axis (e.g., straight, bent, buckled)
- G. hexagonal array orientation when rolled up (e.g., armchair, chiral, zig-zag)
  - chiral or twist angle (the angle between the axis of the hexagonal pattern and the long axis of the nanotube)
- H. particle size of catalyst used in the manufacture of the nanotube
- I. molecular weight (average and range)

J. Particle properties: shape, size (average and distribution), weight (average and distribution), count, surface area (average and distribution), surface to volume ratio, aggregation/agglomeration.

(e) Test Reports. The Company shall: (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; and (3) submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data (“the report and data”) to EPA no later than 14 weeks prior to exceeding the applicable production limit. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall 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 shall be interpreted to mean “shall” to make clear that the submission of such information is mandatory. EPA will not require the submission of raw data such as slides and laboratory notebooks unless 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 and import the PMN substance 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)(1) and (2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substance, 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 and import of the PMN substance beyond the applicable production limit.

(2) The Company may continue to manufacture and import the PMN substance 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) The Company may reconduct the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (f)(3), the Company may exceed the production limit and shall submit the report and data in triplicate 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 and import of the PMN substance 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 and import the PMN substance 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)(1) and (2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate 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 and import beyond the applicable production limit.

(j) Unreasonable Risk.

(1) EPA may notify the Company in writing that EPA finds that the data generated by a study 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, import, 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, import, processing, distribution, use and disposal of the PMN substance, unless either:

(2) within 2 weeks from receipt of the notice described in subparagraph (j)(1), the Company complies with such requirements as EPA's notice specifies; or

(3) within 4 weeks from receipt of the notice described in subparagraph (j)(1), 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, import, 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 shall comply with any requirements imposed by

EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substance.

(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.

### **PROTECTION IN THE WORKPLACE**

(a) Establishment of Program. During manufacturing, processing, and use of the PMN substance at any site controlled by the Company (including any associated packaging and storage and during any cleaning or maintenance of equipment associated with the PMN substance), the Company must establish a program whereby:

(1) General Dermal Protection. Each person who is reasonably likely to be dermally exposed in the work area to the PMN substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne in a form listed in subparagraph (a)(5) of this section, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with OSHA dermal protection requirements at 29 CFR 1910.132, 1910.133, and 1910.138.

(2) Specific Dermal Protective Equipment. The dermal personal protective equipment required by subparagraph (a)(1) of this section must include, but is not limited to, the following items:

- (i) Gloves impervious to the PMN substance
- (ii) full body clothing impervious to the PMN substance

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

(i) Permeation Testing. Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area. Permeation testing shall be conducted according to the American Society for Testing and Materials (ASTM) F739 “Standard Test Method for Resistance of Protective Clothing materials to Permeation by Liquids or Gases.” Results shall be recorded as a cumulative permeation rate as a function of time, and shall be documented in accordance with ASTM F739 using the format specified in ASTM F1194-89 “Guide for Documenting the Results of Chemical Permeation Testing on Protective Clothing Materials.” Gloves may not be used for a time period longer than they are actually tested and must be replaced at the end of each work shift during which they are exposed to the PMN substance.

(ii) Manufacturer’s Specifications. Evaluating the specifications from the

manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the PMN substance alone and in likely combination with other chemical substances in the work area.

(4) Respiratory Protection. Each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substance in the form listed in subparagraph (a)(5) of this section, is provided with, and is required to wear, at a minimum, a NIOSH-certified respirator with an APF of [ ], from the respirators listed in subparagraph (a)(6) of this section, and the respirator is used in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. All respirators must be issued, used, and maintained according to an appropriate respiratory protection program under the Occupational Safety and Health Administration (OSHA) requirements in 29 CFR 1910.134.

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

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

(6) Authorized Respirators. The following NIOSH-certified respirators meet the minimum requirements for subparagraph (a)(4) of this section: Particulate/Aerosol/Mist Exposures, NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters.

## MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture or import of the PMN substance by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall 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) shall 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 shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR.

(b) The Company shall not manufacture the PMN substance other than as [ ]].

(c) The Company shall provide to EPA a 1 gram sample of the PMN substance as specified by EPA in a future written request along with a copy of MSDS for the substance.

### **PROCESSING AND USE**

The Company shall not process or use the PMN substance other than as [ ]].

### **DISTRIBUTION**

(a) Distribution Requirements. Except after the PMN has been completely reacted, the Company shall 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) Not further distribute the PMN substance to any other person, other than for disposal, until after the PMN substance has been completely reacted.

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

(3) Not process and use the PMN substance other than as [

].

(b) Temporary Transport and Storage. Notwithstanding paragraph (a), the Company may distribute the PMN substance outside the Company for temporary transport and storage in sealed containers (labeled in accordance with paragraph (b)(2) of the Hazard Communication Program section of this Order) provided the following two conditions are met:

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

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

(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 (a) of this Distribution section or, after

paragraph (a)(1) expires in accordance with subparagraph (d)(1), has engaged in a significant new use of the PMN substance (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Company shall 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 (a) 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 (a) 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 (a) 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 shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

(d) Sunset Following SNUR. (1) Paragraph (a)(1) of this Distribution section shall 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 (a)(1) of this Distribution section shall 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 (a)(1) of this Distribution section expires in accordance with subparagraph (d)(1), the Company shall 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 invoke 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. After promulgation of a SNUR and expiration of subparagraph (a)(1), such notice may substitute for the written agreement required in the introductory clause of paragraph (a); so that, if the Company provides such notice to the persons to whom it distributes the PMN substance, then the Company is not required to obtain from such persons the written agreement specified in paragraph (a).

### **III. RECORDKEEPING**

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall 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 exemption in Section I, Paragraph (b)(3) 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)(4) 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 shall 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 and importation volume of the PMN substance and the corresponding dates of manufacture and import;

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

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

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

section of this Order;

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

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

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

(9) The Company shall keep a copy of this Order at each of its sites where the PMN substance is manufactured or imported.

(a) 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.

(b) 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 Orders 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 may include, but are not limited to, the following:

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

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

(iii) 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;

(iv) 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;

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

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

(b) Company's Response. The Company shall 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 shall be in writing. To the extent the information is known to or reasonably ascertainable to the Company at the time of the request, the Company's

response shall 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) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

## **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) of TSCA and 40 CFR part 720 before commencing manufacture or 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 shall comply with the terms of this Order and shall 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).

(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 shall 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 C to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to: U.S. Environmental Protection Agency, New Chemicals Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.

(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 or imported. 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 shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

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

(3) Nothing in this section shall 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.

(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 substance manufactured and imported by the Company up to the date of transfer shall 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 health effects of, or human exposure to, the PMN substance, to modify or revoke substantive provisions of this Order. 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 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 proposed therein will not present 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.

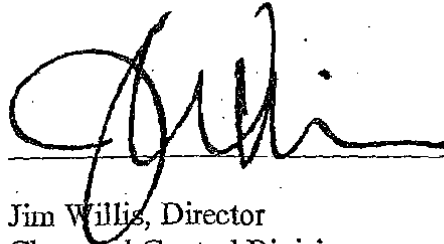
In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the 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.

8/7/08

Date



Jim Willis, Director  
Chemical Control Division  
Office of Pollution Prevention and Toxics

8/11/08

Date

Name:  
Title:  
Company:

EPA SANITIZED



## 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 International Union of Pure and Applied Chemistry or 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 and 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 labelled 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.

“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, imported, 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-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval 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-approved 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.

“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.

“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, shall 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 shall be deemed to apply to all such claims. Where “modifies” is indicated, such modification shall 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.

\_\_\_\_\_  
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

\_\_\_\_\_  
Successor's Technical Contact

\_\_\_\_\_  
Address

\_\_\_\_\_  
City, State, Zip Code

\_\_\_\_\_  
Phone