

September 2004 CO-ContractManuf.X-BasedHH.wpd

## **INSTRUCTIONS FOR PROGRAM MANAGERS**

**Don't forget to delete this Instruction Section from your final Order!**

This Boilerplate Order contains Instructional Notes to Program Managers throughout the text. The notes are in red and bold type in the text to make them easy to find. When the Order is completed make certain that all of these notes have been deleted. To ensure that all notes are deleted, use "Edit, Find and Replace" perform a global search for [**Note to Program Managers**].

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:

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Premanufacture Notice Number:

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Consent Order for Contract Manufacturer

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## CONSENT ORDER

### I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. \_\_\_\_\_ (“the Contract Manufacturer”) has entered into a contract with \_\_\_\_\_ (“the Company”) to manufacture or import exclusively for the Company the chemical substance: \_\_\_\_\_ (P-\_\_ - \_\_\_\_)(“the PMN substance”). The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in the United States by the Contract Manufacturer, except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substance is exempt from the requirements of this Order (except the requirements in the Recordkeeping

and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Contract Manufacturer 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 Contract Manufacturer begins to manufacture the PMN substance for use in the United States, no further activity by the Contract Manufacturer 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.

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

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

and in compliance with 40 CFR 720.30(g).

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

(c) Automatic Sunset. If the Contract Manufacturer 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**

As a condition of manufacturing or importing the PMN substance for the Company, the Contract Manufacturer is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the PMN substance for any non-exempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the health effects **[Note to Program Managers: Edit as appropriate.]** 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**

Triggered Testing Requirements. The Contract Manufacturer 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 the Testing section of the Consent Order for the Company.

<u>Production Limit</u>	<u>Study</u>	<u>Guideline</u>
	Acute Oral Toxicity Study	OPPTS 870.1100 or OECD 425 "Acute Oral Toxicity: Up-Down Procedure"
	Bacterial Reverse Mutation Test	OPPTS 870.5100
	Mammalian Erythrocyte Micronucleus Test (Intraperitoneal route)	OPPTS 870.5395
	Repeated Dose 28-day Oral Toxicity In Rodents - This study should include, for all test doses, a neurotoxicity functional observational battery, as described in OPPTS 870.6200 ("Neurotoxicity screening battery")	OPPTS 870.3050 or OECD 407
	Prenatal Developmental Toxicity Study (one species, oral route)	OPPTS 870.3700

### **MANUFACTURING**

(a)(1) **Prohibition.** The Contract Manufacturer shall not begin manufacture or import of the PMN substance until the Contract Manufacturer or the Company receives a fully executed copy of the Consent Order for Contract Manufacture from EPA.

(2) The Contract Manufacturer shall not cause, encourage, or suggest the manufacture or import of the PMN substance by any other person.

(3) **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 Contract Manufacturer is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Contract Manufacturer is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Contract Manufacturer in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(4) **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 Contract Manufacturer shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR.

### **RISK NOTIFICATION**

(a) If as a result of the test data required under the terms of this Order, the Company or Contract Manufacturer becomes aware that the PMN substance may present a risk of injury to human health (or

is so notified by EPA), the Contract Manufacturer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet ("MSDS"), as described in 40 CFR section 721.72(c), within 90 days from the time the Company or Contract Manufacturer becomes aware of the new information. If the PMN substance is not being manufactured, imported, processed, or used in the Contract Manufacturer's workplace, the Contract Manufacturer must add the new information to an MSDS before the PMN substance is reintroduced into the workplace.

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

### **III. RECORDKEEPING**

(a) Records. The Contract Manufacturer 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 Contract Manufacturer. 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 Contract Manufacturer 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 Contract Manufacturer 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 Contract Manufacturer 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 Contract Manufacturer 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 address, of all sites of manufacture, import, processing, and use;

(5) Copies of material safety data sheets required by the Risk Notification section of this Order;

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

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Contract Manufacturer and its Contract Manufacturer, if applicable, and not to activities of the Contract Manufacturer'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 Contract Manufacturer 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 Contract Manufacturer. 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 Contract Manufacturer facilities and conveyances associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the Contract Manufacturer 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) Contract Manufacturer's Response. The Contract Manufacturer 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 Contract Manufacturer's response shall be in writing. To the extent the information is known to or reasonably ascertainable to the Contract Manufacturer at the time of the request, the Contract Manufacturer'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 Contract Manufacturer submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of

TSCA and 40 CFR Part 2.

## **V. MODIFICATION AND REVOCATION OF CONSENT ORDER**

The Contract Manufacturer may petition EPA at any time, based upon new information on the human health effects of, or human exposures 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 Contract Manufacturer 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**

By consenting to the entry of this Order, the Contract Manufacturer 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 Contract Manufacturer as to, the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Contract Manufacturer may have under TSCA.

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Date

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Wardner G. Penberthey, Acting Director  
Chemical Control Division  
Office of Pollution Prevention and Toxics

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Date

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Name:

Title:

Contract Manufacturer:

## 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 who submitted the pre-manufacture notice (PMN) and who is subject to the Consent Order to which this Consent Order for Contract Manufacturer is an attachment.

"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 this Consent Order for Contract Manufacturer and in Part II. of the Company's Consent Order.

"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.

