UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

CP 1/13/09

1/13/09

In the matter of:	)	Premanufacture Notice Number:
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	)	
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[ ]	)	P04-404
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Consent Order, Consent Order for Contract Manufacturer,
and Determinations Supporting Consent Orders

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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") P04-404 submitted by [ ] ("the Company"), to take effect upon expiration of the PMN review period.

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:

(a) submit to EPA certain toxicity testing in two tiers, at least 14 weeks before manufacturing or importing a total of [ ] and [ ] kilograms, respectively, of the PMN substance;

(b) label containers of the PMN substance and provide Material Safety Data Sheets (MSDSs) and worker training in accordance with the provisions of the Hazard Communication Program section;

(c) distribute the PMN substance only to a person who agrees to follow the same restrictions applicable to the company (except the toxicity testing requirements) and to not further distribute the PMN substance until after it has been completely reacted, cured, or incorporated into a [ ];

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

(e) maintain certain records.

A Consent Order for Contract Manufacturer is attached to extend these requirements to the Contract Manufacturer.

III. CONTENTS OF PMN

Confidential Business Information Claims (Bracketed in the Preamble and Order): Company name; chemical identity; trade identification; production volume; manufacturing, processing and use information.

Chemical Identity:

Specific: [

]

Generic: Tetrabromophthalate Diol Diester

Use:

Specific: [ ]

Generic: Flame Retardant

Maximum 12-Month Production Volume: [ ]

Test Data Submitted with PMN: None.

IV. EPA'S ASSESSMENT OF EXPOSURE AND 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 low molecular weight fraction is expected to be poor via all routes of exposure (dermal, inhalation, and GI tract).

Toxicological Endpoints of Concerns: For the low molecular weight (LMW) components of the PMN substance, there are concerns for liver and kidney toxicity, and for potential to be persistent, bioaccumulative, and toxic (PBT). The Agency estimates that these LMW components of the PMN substance may persist in the environment more than six months, may have a bioaccumulation factor of greater than or equal to 1000, and be potentially toxic over long periods of time. There are also carcinogenicity concerns for the potential formation of brominated [ ] during combustion in municipal incinerators of disposed consumer products containing the PMN substance. The Agency has also determined that the degradation (either metabolic or environmental) products of the PMN substance [ ] may cause liver toxicity.

Basis: Kidney and liver toxicity and PBT concerns are based on test data on structurally similar halogenated esters. (See EPA's Policy Statement on New Chemical PBTs at 64 FR 60194, Nov. 4, 1999, and www.epa.gov/oppt/newchems/pbtpolicy.htm.) Based on available test data on halogenated [ ], the Agency has determined that those chemical substances are probable human carcinogens and may cause toxic effects in aquatic and terrestrial organisms.

Risk to Occupational Workers:

Inhalation exposures are expected to be negligible and, due to low absorption potential and the expectation that the Company will utilize dermal protective equipment, dermal exposures are not expected to pose an unreasonable risk to workers.

Risk to Consumers:

Formulations containing the PMN substance will be used in consumer goods. The Agency has not determined that resulting exposures may present an unreasonable risk to human health. However, based on the PBT potential of the LMW components of the PMN substance, the potential toxicity of the intact PMN substance, and the potential toxicity of the tetrabromophthalate degradation product, EPA does find that there may be significant (or substantial) human exposure to the substance.

Environmental Effects Summary:

Concerns: Chronic toxicity to aquatic organisms. EPA predicts a concern concentration of 3.0 parts per billion (ppb) of the LMW components of the PMN substance.

Basis: Data on halogenated esters structurally similar to the LMW components of parent PMN substance. See http://www.epa.gov/oppt/newchems/chemcat.htm ("Esters") for further information.

Exposure and Environmental Release and Risk Summary:

	Manufacture	Process/ Use
# Sites	[ ]	[ ]
Workers (#/site)	[ ]	[ ]

Exposure (days/year)	[ ]	[ ]
Dermal Exposure (mg/day)	up to 1,764	up to 1,764
Inhalation Exposure (mg/day)	negligible	negligible
Drinking Water Exposure (mg/kg/day)	none	1×10^{-6} (average daily dose)
Releases (days/year)	NA	1
Release to Water (kg/site/day)	not expected[1]	1.28[2]
Surface Water Concentration (ppb)	NA	89
Days Exceeding Aquatic Toxicity Concern Concentration	NA	1

In the absence of regulation, additional releases to surface waters and PBT concerns associated with the PMN substance may present an unreasonable risk to the environment.

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 adverse effects from exposure of humans and aquatic organisms to the LMW components of the PMN substance and potential breakdown products of the PMN substance. Further EPA is unable to determine the potential for human

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[1]Reactor cleaned with solvent, which is recycled into the next batch. Worst case 580 kg/yr of PMN substance disposed of via incineration.

[2]In lieu of releases to water, these releases from cleaning residuals from dedicated shipping containers could go to landfill (32 kg/yr) or incineration (160 kg/yr)

health and environmental effects from by-products potentially formed during incineration of [ ] containing 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 and environmental effects of the PMN substance.

B. In light of the potential risk of environmental effects posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance, and the Agency's conclusion that issuing the Order will not result in any significant loss of benefits to society, 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 the environment.

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

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

The Order prohibits the Company from exceeding a specified 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'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.

CONSENT ORDER

I. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

[ ] ("the Company") is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the chemical substance [ ], diacetate] (P04-404) ("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 under the following conditions:

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substance which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or the environment, which is 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 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 68 Federal Register 33129 (June 3, 2003).

(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, NW, 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; and

3. The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study.

4. The appropriate PMN identification number for each 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 4O CFR Part 792 and using methodologies generally accepted at the time the study is initiated. Before starting to conduct any 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.

(d) Triggered Testing Requirements. The Company is prohibited from manufacturing or importing, or causing another person to manufacture or import, 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.

Production Limit	Study	Guideline
Tier 1:		
[ ]	Algal Toxicity Test	OPPTS 850.5400
	Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids	OPPTS 850.1010
	Fish Acute Toxicity Test	OPPTS 850.1075
	Either: 1) Shake-flask Die-away Test, or 2) Aerobic and Anaerobic Transformation in Aquatic Sediments, or an equivalent test (including identification of breakdown products)	OPPTS 835.3170, OECD 308
	Either: 1) Fish BCF; or 2) Bioconcentration: Flow-through Fish Test; or an equivalent test. (Measured BCF (bioconcentration factor) should be based on 100 percent active ingredient and measured concentration(s))	OPPTS 850.1730 OECD 305
	Incineration Simulation Study	Consult with the Agency for protocol
	Porous Pot (sewage treatment simulation)	OPPTS 835.3220

Tier 2: [	]	Migration Study from final foam products	Consult with the Agency for protocol
		Two Generation Reproduction Study: rats, oral route, modified with complementary blood chemistry and histopathology from the 90-day oral study protocol	OPPTS 870.3800, combined with OPPTS 870.3100
		Developmental Toxicity Study: rats, oral route	OPPTS 870.3700

(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 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 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 (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 (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 IV. of this Consent Order.

HAZARD COMMUNICATION PROGRAM

(a) Written Hazard Communication Program. The Company shall develop and implement a written hazard communication program for the PMN substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The Company must make the written hazard communication program available, upon request, to all employees, contractor employees,

and their designated representatives. The Company may rely on an existing hazard communication program, including an existing program established under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1910.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program shall include the following:

(1) A list of chemical substances known to be present in the work area which are subject to a TSCA section 5(e) consent order signed by the Company or to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E. The list must be maintained in each work area where the PMN substance is known to be present and must use the identity provided on the MSDS for the substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Company is required either by another Order issued under section 5(e) of TSCA or by a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, to maintain a list of substances, the lists shall be combined with the list under this subparagraph.

(2) The methods the Company will use to inform employees of the hazards of non-routine tasks involving the PMN substance (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substance contained in unlabeled pipes in their work area.

(3) The methods the Company will use to inform contractors of the presence of the PMN substance in the Company's workplace and of the provisions of this Order if employees of the contractor work in the Company's workplace and are reasonably likely to be exposed to the PMN substance while in the Company's workplace.

(b) Labeling. (1) The Company shall ensure that each container of the substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(A) A statement of the health hazards(s) and precautionary measure(s), if any, identified in paragraph (g) of this section or by the Company, for the PMN substance.

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

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

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

(ii) The Company may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Company need not label portable containers into which the PMN substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Company shall not remove or deface an existing label on containers of the PMN substance obtained from persons outside the Company unless the container is immediately relabeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Company shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(A) The information prescribed in subparagraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance that is either subject to another TSCA section 5(e) Order applicable to the Company, or subject to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, or defined as a "hazardous chemical" under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), the Company may prescribe on the label, MSDS, or alternative form of warning, the measures to

control worker exposure or environmental release which the Company determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Company must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

(c) Material Safety Data Sheets. (1) The Company must obtain or develop an MSDS for the PMN substance.

(2) The MSDS shall contain, at a minimum, the following information:

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

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

(iii) The physical hazards of the substance known to the Company, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (g) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substance known to the Company.

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

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Company, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Company, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Company.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Company or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Company must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Company may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Company becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured, imported, processed, or used in the Company's workplace, the Company must add the new information to the MSDS before the PMN substance is reintroduced into the workplace.

(6) The Company must ensure that persons receiving the PMN substance from the Company are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Company may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Company must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee Information and Training. The Company must ensure that employees are provided with information and training on the PMN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substance and whenever the PMN substance is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the PMN substance is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substance in or from an employee's work area (such as monitoring conducted by the Company, continuous monitoring devices, visual appearance, or odor of the substance when being released).

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

(iii) The measures employees can take to protect themselves and the environment from the PMN substance, including specific procedures the Company has implemented to protect employees and the environment from exposure to the PMN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and

other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Company under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) Low Concentrations in Mixtures. If the PMN substance is present in the work area only as a mixture, the Company is exempt from the provisions of this section if the concentration of the PMN substance in the mixture does not exceed 1.0 percent by weight or volume, or 0.1 percent by weight or volume if paragraph (g) of this section identifies cancer as a potential human health hazard of the PMN substance. However, this exemption does not apply if the Company has reason to believe that during intended use or processing in the work area, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever is applicable.

(f) Existing Hazard Communication Program. The Company need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(g) Human Health, Environmental Hazard, Exposure, and Precautionary Statements. The following human health and environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) and the MSDS as specified in paragraph (c) of this section:

(1) Human health hazard statements. This substance may cause:

(i) internal organ effects.

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

(i) avoid skin contact.

(ii) use skin protection.

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

(i) toxic to fish.

(ii) toxic to aquatic organisms.

(4) Environmental hazard precautionary statements. Notice to users:

(i) do not release to water.

(5) The human and environmental hazard and precautionary statement contained on a label prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the MSDS for details."

MANUFACTURING

(a) The Company shall not cause, encourage, or suggest the manufacture and/or import of the PMN substance by any other person outside the Company, except a Contract Manufacturer as described in paragraph (b).

(b) Notwithstanding paragraph (a), the Company may cause a "Contract Manufacturer" outside the Company to manufacture and/or import the PMN substance according to the following conditions:

(1) The Contract Manufacturer must be under contract to the Company to manufacture or import the PMN substance solely for the Company. The contract must specify the identity of the PMN substance, the total quantities to be manufactured, and the basic technology to be used for manufacturing.

(2) The Company shall obtain from each Contract Manufacturer a signed copy of the Consent Order for Contract Manufacturer (attached to this Order as Attachment C) and submit the copy to EPA along with the name, address, and telephone number of a responsible official of the Contract Manufacturer. The Contract Manufacturer or Company must receive a fully executed copy of the Consent Order for Contract Manufacturer from EPA before the Contract Manufacturer may begin manufacture or import.

(3) If, at any time, the Company learns that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture or import of the PMN substance, unless the Contract Manufacturer is in compliance with a SNUR for the PMN substance, or unless the Company is able to document each of the following:

(A) That the Company has, within 5 working days, notified the Contract Manufacturer in writing that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer.

(B) That, within 15 working days of notifying the Contract Manufacturer of the noncompliance, the Company received from the Contract Manufacturer, in writing, a statement of assurance that the Contract Manufacturer is aware of the terms of the Consent Order for Contract Manufacturer and will comply with those terms.

(C) If, after receiving a statement of assurance from the Contract Manufacturer under subparagraph (B) of this Section, the Company has notice or knowledge that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for

Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture or import the PMN substance, shall notify EPA of the failure to comply, and shall resume causing the Contract Manufacturer to manufacture or import the PMN substance only upon written notification from the Agency.

(c)(1) Sunset Following SNUR. Paragraph (a) 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, paragraph (a) 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) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and paragraph (a) expires in accordance with subparagraph (c)(1), 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. 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.

(3) Subparagraph (c)(1) shall not negate the effect of any fully executed Consent Order for Contract Manufacturer entered into under subparagraph (b)(2).

DISTRIBUTION

(a) Distribution Requirements. Except as provided in paragraph (b), the Company shall distribute the PMN substance outside the Company, including 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, including for disposal, until after the PMN substance has been completely reacted, cured, or incorporated into a [

].

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

(3) Comply with the same environmental release restrictions, if any, required of the Company in the Release to Water section of this Order.

(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 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).

RELEASE TO WATER

The Company is prohibited from any predictable or purposeful release of the PMN substance, or any waste stream from manufacturing, processing, or use into the waters of the United States.

II. RECORD-KEEPING

(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) Records documenting the aggregate manufacture and importation volume of the PMN substance and the corresponding dates of manufacture and import;

(2) 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;

(3) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(4) Copies of labels required under the Hazard Communication Program section of this Order;

(5) Copies of Material Safety Data Sheets required by the Hazard Communication Program section of this Order;

(6) Records documenting compliance with any applicable manufacturing and distribution restrictions in the Manufacturing and Distribution sections of this Order;

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

(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, imported, processed or used.

(b) Applicability. The provisions of this Record-keeping 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.**

III. 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 is not 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(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 (7405M), 1200 Pennsylvania Avenue, NW, 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 and time 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 and time 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 and time 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.

IV. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health or environmental effects of, human exposure to, or environmental release of, 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.

V. 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, or modifications made thereto, in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, does 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.

_____ _____

Date

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

_____ _____

Date

Name:

Title:

Company: [ ]

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 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.

"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

[_____] _____ P04-404 ____

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(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.

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

[ ]
Company (Transferor)

P04-404
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

ATTACHMENT C

CONTAINS NO CBI

(P/13/09

1/13/09

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:
	)	
	)	
	)	
	)	
	)	
[ ]	)	P04-404
	)	
	)	
	)	
	)	
	)	

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Consent Order for Contract Manufacturer

CONSENT ORDER

I. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

[ ] ("the Contract Manufacturer") has entered into a contract with [ ] ("the Company") to manufacture or import exclusively for the Company the chemical substance [ ] (P04-404) ("the PMN substance").

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 and environmental effects of the substance, and the completion of EPA's review of, and regulatory action based on that information except under the following conditions:

TESTING

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:

Production Limit			Guideline
Tier 1:			
[	]	1) Shake-flask Die-away Test, or	
		2) Aerobic and Anaerobic Transformation in Aquatic Sediments, or	OPPTS 850.5400 OPPTS 850.1010 OPPTS 850.1075
		an equivalent test (including identification of breakdown products)	OPPTS 835.3170,
		Either: 1) Fish BCF; or 2) Bioconcentration: Flow-through Fish Test; or an equivalent test. (Measured BCF (bioconcentration factor) should be based on 100	OECD 308 OPPTS 850.1730 OECD 305

Study

Algal Toxicity
Acute Daphnid Toxicity
Fish Acute Toxicity

Either:

		percent active ingredient and measured concentration(s))	
		Porous Pot (sewage treatment simulation)	
		OPPTS 835.3220	
Tier 2: [	]	Migration Study from final foam products	Consult with the Agency for protocol
		Two Generation Reproduction Study: rats, oral route, modified with complementary blood chemistry and histopathology from the 90-day oral study protocol	OPPTS 870.3800, combined with OPPTS 870.3100
		Developmental Toxicity Study: rats, oral route	OPPTS 870.3700

HAZARD COMMUNICATION PROGRAM

(a) Written Hazard Communication Program. The Contract Manufacturer shall develop and implement a written hazard communication program for the PMN substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The Contract Manufacturer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Contract Manufacturer may rely

on an existing hazard communication program, including an existing program established under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1910.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program shall include the following:

(1) A list of chemical substances known to be present in the work area which are subject to a TSCA section 5(e) consent order signed by the Contract Manufacturer or to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E. The list must be maintained in each work area where the PMN substance is known to be present and must use the identity provided on the MSDS for the substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Contract Manufacturer is required either by another Order issued under section 5(e) of TSCA or by a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, to maintain a list of substances, the lists shall be combined with the list under this subparagraph.

(2) The methods the Contract Manufacturer will use to inform employees of the hazards of non-routine tasks involving the PMN substance (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substance contained in unlabeled pipes in their work area.

(3) The methods the Contract Manufacturer will use to inform contractors of the presence of the PMN substance in the Contract Manufacturer's workplace and of the provisions of this Order if employees of the contractor work in the Contract Manufacturer's workplace and are reasonably likely to be exposed to the PMN substance while in the Contract Manufacturer's workplace.

(b) Labeling. (1) The Contract Manufacturer shall ensure that each container of the substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(A) A statement of the health hazards(s) and precautionary measure(s), if any, identified in paragraph (g) of this section or by the Contract Manufacturer, for the PMN substance.

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

(C) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified in paragraph (g) of this section, or by the Contract Manufacturer, for the PMN substance.

(D) A statement of exposure and precautionary measure(s), if any, identified in paragraph (g) of this section, or by the Contract Manufacturer, for the PMN substance.

(ii) The Contract Manufacturer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Contract Manufacturer need not label portable containers into which the PMN substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Contract Manufacturer shall not remove or deface an existing label on containers of the PMN substance obtained from persons outside the Contract Manufacturer unless the container is immediately relabeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Contract Manufacturer shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(A) The information prescribed in subparagraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance that is either subject to another TSCA section 5(e) Order applicable to the Contract Manufacturer, or subject to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, or defined as a "hazardous chemical" under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), the Contract Manufacturer may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Contract Manufacturer determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Contract Manufacturer must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

(c) Material Safety Data Sheets. (1) The Contract Manufacturer must obtain or develop an MSDS for the PMN substance.

(2) The MSDS shall contain, at a minimum, the following information:

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

(ii) Physical and chemical characteristics of the substance known to the Contract Manufacturer, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the substance known to the Contract Manufacturer, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (g) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substance known to the Contract Manufacturer.

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

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Contract Manufacturer, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Contract Manufacturer, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Contract Manufacturer.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Contract Manufacturer or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Contract Manufacturer must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Contract Manufacturer may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Contract Manufacturer becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the 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 the MSDS before the PMN substance is reintroduced into the workplace.

(6) The Contract Manufacturer must ensure that persons receiving the PMN substance from the Contract Manufacturer are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Contract Manufacturer may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Contract Manufacturer must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee Information and Training. The Contract Manufacturer must ensure that employees are provided with information and training on the PMN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substance and whenever the PMN substance is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the PMN substance is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substance in or from an employee's work area (such as monitoring conducted by the Contract Manufacturer, continuous monitoring devices, visual appearance, or odor of the substance when being released).

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

(iii) The measures employees can take to protect themselves and the environment from the PMN substance, including specific procedures the Contract Manufacturer has implemented to protect employees and the environment from exposure to the PMN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Contract Manufacturer under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) Low Concentrations in Mixtures. If the PMN substance is present in the work area only as a mixture, the Contract Manufacturer is exempt from the provisions of this section if the concentration of the PMN substance in the mixture does not exceed 1.0 percent by weight or volume, or 0.1 percent by weight or volume if paragraph (g) of this section identifies cancer as a potential human health hazard of the PMN substance. However, this exemption does not apply if

the Contract Manufacturer has reason to believe that during intended use or processing in the work area, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever is applicable.

(f) Existing Hazard Communication Program. The Contract Manufacturer need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(g) Human Health, Environmental Hazard, Exposure, and Precautionary Statements. The following human health and environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) and the MSDS as specified in paragraph (c) of this section:

(1) Human health hazard statements. This substance may cause:

(i) internal organ effects.

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

(i) avoid skin contact.

(ii) use skin protection.

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

(i) toxic to fish.

(ii) toxic to aquatic organisms.

(4) Environmental hazard precautionary statements. Notice to users:

(i) do not release to water.

(5) The human and environmental hazard and precautionary statement contained on a label prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the MSDS for details."

MANUFACTURING

(a)(1) The Contract Manufacturer shall not cause, encourage, or suggest the manufacture and/or import of the PMN substance by any other person, except the Contract Manufacturer.

(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 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.

(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 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. 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.

DISTRIBUTION

(a) Distribution Requirements. The Contract Manufacturer shall distribute the PMN substance only to the Company.

(b)(1) Sunset Following SNUR. Paragraph (a) 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 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, paragraph (a) of this Distribution section 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.

(2) When EPA promulgates a final SNUR for the PMN substance and paragraph (a) of this Distribution section expires in accordance with subparagraph (b)(1), the Contract Manufacturer 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.

(c) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substance, the Contract Manufacturer obtains knowledge that a recipient of the PMN substance 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 Contract

Manufacturer shall cease supplying the substance to that recipient, unless the Contract Manufacturer is able to document each of the following:

(1) That the Contract Manufacturer has, within 5 working days, notified the recipient in writing that the recipient 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 Contract Manufacturer received from the recipient, in writing, a statement of assurance that the recipient 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 (b)(2) of this Distribution section, the Contract Manufacturer obtains knowledge that the recipient has again engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA, the Contract Manufacturer 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.

DISPOSAL

Whenever the Contract Manufacturer disposes of the PMN substance by incineration, the incinerator must operate at temperatures equal to or greater than 800 degrees Celsius (+/- 100 degrees) with a 2 second minimum residence time.

RELEASE TO WATER

The Contract Manufacturer is prohibited from any predictable or purposeful release of the PMN substance, or any waste stream from manufacturing, processing, or use into the waters of the United States.

II. RECORD-KEEPING

(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) Records documenting the aggregate manufacture and importation volume of the PMN substance and the corresponding dates of manufacture and import;

(2) 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;

(3) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(4) Copies of labels required under the Hazard Communication Program section of this Order;

(5) Copies of Material Safety Data Sheets required by the Hazard Communication Program section of this Order;

(6) Records documenting compliance with any applicable manufacturing and distribution restrictions in the Manufacturing and Distribution sections of this Order;

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

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

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

(10) Records documenting compliance with any applicable disposal requirements under the Disposal section of this Order, including method of disposal, location of disposal sites, dates of disposal, and volume of PMN substance disposed. Where the estimated disposal volume is not known to the Contract Manufacturer and is not reasonably ascertainable by the Contract Manufacturer, the Contract Manufacturer must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements.

(b) Applicability. The provisions of this Record-keeping Section are applicable only to the Contract Manufacturer, if applicable, and not 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 Order has been approved under currently valid **OMB Control Number 2070-0012.**

IV. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Contract Manufacturer may petition EPA at any time, based upon new information on the health or environmental effects of, human exposure to, or environmental release of, 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.

V. 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, or modifications made thereto, in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, does 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.

_____ _____

Date

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

_____ _____

Date

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 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 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.

"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.