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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF NEW CHEMICAL SUBSTANCES

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Numbers:
	)	
	)	
	)	
	)	
	)	
DuPont Company	)	P-08-508 and P-08-509
	)	
	)	
	)	EPA SANITIZED
	)	
	)	

Consent Order and Determinations Supporting Consent Order

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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 notices ("PMNs") P-08-508 for the chemical substance [ ] and P-08-509 for the chemical substance [ ] ("the PMN substances") submitted by DuPont Company ("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMNs to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for these PMN substances requires the Company to:

(a) submit to EPA certain toxicity and pharmacokinetics testing on the PMN substance described in P-08-509 at least 14 weeks before manufacturing or importing a total of [ ] kilograms (kgs) of the two PMN substances (or 2 years, whichever comes later, for two of the studies) and [ ] kgs of the two PMN substances combined;

(b) require any workers who may be exposed to wear impervious gloves and distribute the PMN substances to only those customers that agree to require impervious gloves;

(c) require any workers who may be exposed via inhalation to P-08-508 to wear a respirator with a NIOSH Assigned Protection Factor ("APF") of 3000 and distribute to only those customers that agree to require those respirators;

(d) require any workers who may be exposed via inhalation to P-08-509 to wear an appropriate NIOSH-approved respirator and distribute only to customers that agree to require respirators for any workers reasonably likely to be exposed by inhalation;

(e) as an alternative to using respirators, maintain workplace airborne concentrations of the PMN substances in the United States at or below a specified New Chemical Exposure Limit ("NCEL") of 0.01 mg/m3 (based on the current ACGIH TLV/TWA for the ammonium salt of perfluorooctanoic acid ("APFO")) and distribute only to those customers in the United States that maintain this NCEL. (To pursue this option, a sampling and analytical method must be developed by the Company, verified by an independent third-party laboratory, and submitted to EPA.);

(f) for operations in the United States, recover and capture (destroy) or recycle the PMN substances from all the process wastewater effluent streams and air emissions (point source and fugitive) at an overall efficiency of 99% and distribute only to those customers that achieve this percentage of efficiency or destruction;

(g) distribute the polymers containing the PMN substances (residuals) at levels not to exceed those specified in this Order and verified using the method in Larsen et al. (2006);

and

(h) maintain certain records.

III. CONTENTS OF PMN

Confidential Business Information Claims (Bracketed in the Preamble and Order): specific chemical identity, production volume, manufacturing process and sites, processing, use, and other information

Chemical Identities:

Specific: **P-08-508** [ ]

CAS no.: [ ] and **P-08-509** [

] CAS no.: [ ].

Generic chemical identity: **P-08-508**– Perfluorinated aliphatic carboxylic acid and **P-08-509**–Perfluorinated Aliphatic Carboxylic Acid, Ammonium Salt

Use:

Specific: **P-08-508**-[

] and **P-08-509**-[

] Intended to replace [

]

Generic: **P-08-508**-Intermediate for polymerization aid, **P-08-509**-polymerization aid

Maximum 12-Month Production Volume: **P-08-508**-[ ] kgs, **P-08-509**-[ ] kgs

Test Data Submitted with PMN: Physical and Chemical characteristics; Determination of the Dissociation Constant (salt); Determination of Water Solubility and Vapor Pressure; Biopersistence and Pharmacokinetic Screen in the Rat; In Vitro Trout Hepatocyte

Bioaccumulation Screen; Thermal Decomposition Study results

Toxicity: Acute oral toxicity, up-and-down procedure and Acute Oral Test (rats and mice); Approximate Lethal Dose (ALD) in rats and mice; Acute Dermal Toxicity in Rats; Approximate Lethal Dose (ALD) by Skin Absorption in Rabbits; Local Lymph Node Assay (LLNA) in Mice; Acute Eye Irritation in rabbits; Acute Dermal Irritation Study in Rabbits; 7-day Repeated Dose Oral Toxicity in Rats and Male Mice; 28-Day Repeated Dose Oral Toxicity Study in Rats and Mice; Corrositex in vitro test; Combined Two Week Inhalation Toxicity and Micronucleus Studies in Rats-Transformation Byproduct. In Vitro Micronucleus and Chromosome Abberration Assay in Mouse Bone Marrow Cells; In Vitro Rat Hepatocyte Screen, Bacterial Acute Mutation test; Determination of permeabillity coefficient (Kp) using a static in vitro diffusion cell model; In Vitro evaluation for Chromosome Aberrations in Human Lymphocytes-transformation byproduct

Mutagenicty test in Salmonella Typhimurium-transformation; byproduct; Combined two week inhalation toxicity and micronucleus studies in -transformation byproduct; Water solubility, vapor pressure, and octanol water partition coefficient and other p-chem properties of transformation byproduct; Thermal Transformation Byproduct

Ecotoxicity/Fate: Acute toxicity to fish (Rainbow trout), daphnia, and algae; Ready Biodegradability Study; Activated Sludge Respiration Inhibition Test; and Assessment of Hydrolysis as a Function of pH

In general, the test substance was the salt (509), except for some acute studies, pharmacokinetics, and mutagenicity where the test substance was both the acid (508) and the salt (509) or as noted below. For a complete listing, see the PMN.

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

Human Health Effects and Fate Summary:

EPA has concerns that these PMN substances will persist in the environment, could bioaccumulate, and be toxic ("PBT") to people, wild mammals, and birds. EPA's concerns are based on data on the PMN substances, analogy to other [ ] chemicals, and to perfluorooctanoic acid ("PFOA") and perfluorooctane sulfonate ("PFOS") which are both currently under review by EPA for PBT concerns. Some [ ], PFOA, and PFOS are expected to persist for years in the environment. Biodegradation and photolysis tests of some analogous substances indicate little or no biodegradation or photolysis of perfluoroalkyl compounds. Bioaccumulation concerns are based on the measured presence of certain perfluoroalkyl compounds, including PFOA, in wildlife and in human blood samples.

Based on test data on structurally similar [ ] chemicals and data on the PMN substances themselves, EPA has human health concerns for the PMN substances. The PMN substances are expected to be absorbed by all routes of exposure. The PMN substances show low acute oral toxicity ($\geq$ 3400 mg/kg). The acute dermal toxicity study with P-08-509 shows low acute dermal toxicity (>5000mg/kg). The PMN substance P-08-508 is expected to be highly irritating or corrosive. There is high concern for eye irritation for both PMN substances.

The PMN substance P08-509 was tested in a 28-day repeated dose study in rats and mice. In the rat study, the doses were 0, 0.3, 3, and 30 mg/kg/day in males and 0, 3, 30, and 300 mg/kg/day in females. The EPA reviewer set the NOAEL in males at 0.3 mg/kg/day based on dose related trends and statistical significance of change in hematologic findings (decreases in red blood cell counts, hemoglobin, and hematocrit in males), increase in clinical chemistry, increases in absolute and relative organ/body and liver weights. Histopathologic findings in the liver included minimal or mild hepatocellular hypertrophy in males at 3 and 30 mg/kg/day. In this study in rats, the EPA reviewer set the NOAEL at 30 mg/kg/day in females based on increased liver weights and liver pathology as hepatocellular hypertrophy in females given 300 mg/kg/day. The investigators concluded that the NOAELs were 30 mg/kg/day in males and 300 mg/kg/day in females, stating that all changes in treated groups are within historical control ranges at the testing facility and as adaptive responses.

In the mouse study, the doses were 0 (vehicle control), 0.1, 3, or 30 mg/kg/day of test substance in deionized water by gavage daily for 28 days with terminal sacrifice on day 29. In addition, 10 male and female mice were similarly treated with 0 (vehicle control), 30 (males), or 300 (females) mg/kg/day and killed after 28 days of recovery following treatment.
The EPA reviewer set the NOAEL at 0.1 mg/kg/day based on signs of anemia and liver effects at higher dose levels. The investigators placed the NOAEL at 0.1 mg/kg/day in males and 3 in females.

A related [ ] substance was also tested in a 28-day study in rats. The doses were 0, 5, 25, and 100 mg/kg/day with a NOAEL of 5 mg/kg/day and effects on the liver and kidney at 25 and 100 mg/kg/day. A single dose pharmacokinetic study was conducted in the rat and the

monkey. Male and female results were similar. Toxicity studies on some [ ] have shown systemic toxicity in animals at levels as low as 0.13 mg/kg in a 90-day oral toxicity study.

Some data exists on the transformation product [ ] and [ ] in combined two week inhalation toxicity and micronucleus studies. Doses were 0, 5,000, 25,000 and 175,000 ppm. The NOAEL was determined to be 175,000 ppm. No systemic toxicity relevant to humans was exhibited for [ ]. For [ ], increased absolute and relative liver weights were seen in this limited study at 25,000 ppm. Mutagenicity in this study was negative.

Several mutagenicity studies were conducted on both PMN substances, P-08-508 and 509. They were not gene mutagens in two species of prokaryotes, and not inducers of DNA effects in mammalian cells *in vivo*. They were chromosome mutagens in mammalian and human cells in culture, but not in mammals *in vivo*. The EPA reviewer concluded that the positive data on the PMNs for *in vitro* chromosomal aberrations in mammalian and human cells are of some concern. However, the negative responses for *in vivo* chromosomal effects as micronuclei and as chromosomal aberrations, and for induction of DNA effects, alleviates that concern. No additional mutagenicity testing is recommended.

For chronic and carcinogenic effects, no information was submitted. EPA believes that a 2-year Chronic Toxicity/Carcinogenicity study (OPPTS 870.~~3100~~, OECD 453) is needed.

Pharmacokinetic studies were conducted in rats. Groups of 3 male and 3 female rats were dosed via single oral gavage with either 10 or 30 mg/kg of the PMN substance P-08-508 (98%) and P-08-509 (84.5%). Blood samples were taken before dosing and periodically thereafter up to 168 hours (7 days) after dosing. In addition, fat and liver samples were taken at terminal sacrifice. Samples were analyzed for the parent compound using HPLC/MS with a level of

quantitation (LOQ) at 20 ng/ml. Clearance times were calculated for the 2 doses for males and females as follows:

	10 mg/kg (508)	30 mg/kg (508)	10 mg/kg (509)	30 mg/kg (509)
Male	28 hr	22 hr	12 hr	22 hr
Female	8 hr	4 hr	4 hr	8 hr

The Company has done some limited biomonitoring in workers and site monitoring. EPA has reviewed the biomonitoring and concluded that samples did not take place over a long enough period of time to see if accumulation occurred and that the limit of detection was not sensitive enough to draw any conclusions at this time.

Toxicity studies on the analogs PFOA and PFOS indicate developmental, reproductive and systemic toxicity in various species. Cancer may also be of concern. These factors, taken together, raise concerns for potential adverse chronic effects in humans and wildlife. For additional information about PFOA, consult the docket EPA-HQ -OPPT-2003-0013. Additional information about PFOA and other perfluorinated substances may also be found in the *Administrative Record for PFOS, PFOA, and Telomers and Related Chemicals (AR-226). Administrative Record (AR-226)* is not currently available online, but copies can be requested on CD-ROM from the EPA Docket office by calling 202/566-0280 or sending an email request to oppt.ncic@epa.gov.

The data on the PMN substance and some other data indicate a different and less toxic profile for the PMN substances than for PFOA and PFOS. However, based on: 1) the persistence of the PMN substances, 2) the toxicity of the PMN substances and some of the [ ] analogs, and 3) the possibility or likelihood that this substance may be used as

a major substitute for a major use of PFOA, EPA believes that more information is needed on the toxicity and pharmacokinetics of the PMN substance P-08-509 that will be applied to the characterization of both PMN substances.

EPA believes that additional pharmacokinetic, reproductive, and long-term toxicological testing on the PMN substance P-08-509 in animals is warranted. EPA will require at a certain production volume that a modified reproductive test (OECD 421, modified) be conducted. The modifications for the reproductive test include: (1) increase the parental sample size to 20; (2) the duration of the study should be extended to until the pups have reached sexual maturation; (3) parental males should be dosed for 10 weeks prior to mating; (4) dosing of the parental animals should be continued through lactation and then the pups should be directly dosed until they reach sexual maturation; (5) pup body weight should be recorded on lactation days 0, 4, 7, 14, and 21 and then at weekly intervals, (6) litter size can be standardized to 4 pups/litter on lactation day 4 (optional); (7) at weaning one pup/sex/litter shall be randomly selected to follow until sexual maturation; and (8) the time of sexual maturation should be recorded (i.e. vaginal opening and preputial separation). In addition, the Company will also conduct Repeated Dose Pharmacokinetics and Metabolism testing (OPPTS 870.7485); a Combined Carcinogenicity/Chronic Toxicity test (OPPTS 870.4300/OECD 453); and an Avian Reproduction test (OECD 206, OPPTS 850.2300).

Environmental Effects Summary:

EPA expects the PMN substances to be highly persistent in the environment. In addition, they may be bio-accumulative or biopersistent based on the predicted log Koc and because some

related substances show evidence of biopersistence. No short-term ecotoxicological concerns were raised for the PMN substances. Reported results in acute toxicity tests in fish (rainbow trout), Daphnia magna and green algae were: fish–96 hr LC 50>96.9 mg/l; Daphnia magna 48 hr EC50 > 102 mg/l; and 72 hr EC50>106 mg/l. However, there is high concern for possible environmental effects over the long-term. As stated previously, the analog PFOA is persistent in the environment and has a long bioretention time in various species. It has been detected in a number of species of wildlife, including marine mammals. It is toxic to mammalian and other species. The presence in the environment and toxicological properties of PFOA continue to be investigated. EPA believes development of additional data is warranted. EPA will require at a certain production volume that a Fish Early Life Stage Toxicity test (OPPTS 850.1400), a Daphnid Chronic Toxicity test (OPPTS 850.1300), and an Avian Reproduction test-Bobwhite Quail (OPPTS 850.2300) be conducted.

Exposure and Environmental Release Summary:

These PMN substances will be manufactured by [

]. P-08-509 will be used as a polymerization aid in the manufacture of [ ].

Several points of exposure and release were submitted and evaluated for these PMN substances. Doses were calculated for dermal and inhalation exposure to P-08-508 from loading and unloading drums and sampling. Inhalation exposures are to vapors with up to 20 workers potentially exposed. EPA estimates that these quantities could be between 3.8 mg/day (typical) to 230 mg/day (worst case). There may be dermal exposure to a liquid containing P-08-508. For P-08-509, manufacture and use were assumed at up to 3 sites (2 DuPont sites and one potential customer site). According to the Company, only one site will be used at a time. At these sites, the material will be unloaded and charged to various process vessels, such as a blend tank or a polykettle. Due to the low vapor pressure of P-08-509, only dermal exposure was evaluated. Based on the possibility of inadvertent exposure at low levels, the Order requires that any person who is reasonably likely to be exposed by inhalation to the PMN substance P-08-509 to wear an appropriate NIOSH-approved respirator. EPA has established for both PMN substances a New Chemical Exposure Limit ("NCEL") at 0.01 mg/m3, the Threshold Limit Value ("TLV") currently recommended for APFO by the ACGIH in the United States, in order to "level the playing field" and allow the substitution of the PMN substance P-08-509 into the marketplace. EPA believes that this limit should be adequate for the PMN substances based on current information. If this ACGIH level were to change or there is data on the PMN substances that EPA believes warrants a change, the NCEL may be changed in order to correspond with the new level or data.

Releases to the environment were estimated to water and to air (fugitive) and to air via incineration. Based on submitter information, the Company currently collects the waste containing the PMN substances and sends the waste to an off-site RCRA incinerator. In the future, the Company intends to develop and use methods to recapture and/or recycle the substances, but is not now doing so. EPA requires in the attached Consent Order that the substances be recovered, recycled and/or destroyed at levels achieving 99% efficiency. EPA will require that the Company directly sell the substances only to customers, if any, that achieve comparable recovery or destruction. The Company shall distribute the PMN substance, P-08-509 in polymers, aqueous or solid, so that the residual P-08-508/509 cumulative total [

] are below 200 ppb level using the ASE method developed by Larsen et al. (The Analyst 2006 p. 1105) with the level of quantification (LOQ) for the standard solution at 0.5 ppb. If non-heat treated solid polymer is distributed then the substance cannot be further distributed, until it is sufficiently heat treated. The Company should make every effort to minimize or prevent any release to the environment of these substances. If any new uses of the substance are found, the Company shall find ways to recover and/or recycle the substance to comparable levels. Fugitive releases may be of particular concern.

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

A. EPA is unable to determine the potential for human health and environmental effects from exposure to the PMN substances. 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 substances.

B. In light of the potential risk of human health and environmental effects posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances, 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 substances may present an unreasonable risk of injury to human health and the environment.

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

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Triggered Testing. The Order prohibits the Company from exceeding specified production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.

Pended Testing. The Order does not require submission of the following information at any specified time or production volume. However, the Order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances will

remain in effect until the Order is modified or revoked by EPA based on submission of the following or other relevant information.

Fate and Physical/Chemical Properties information as follows:

Physical/Chemical Property Testing	**OPPTS or OECD Guideline**
UV visible absorption	OPPTS 830.7050 or OECD 101
Hydrolysis as a function of pH	OPPTS 835.2130 or OECD 111

Environmental Fate Testing	**OPPTS or OECD Guideline**
Modified Semi-Continuous Activated Sludge (SCAS) with Analysis for degradation products	OPPTS 835.5045, OPPTS 835.3210 or OECD 302A
Aerobic and Anaerobic Transformation in Soil	OECD 307
Aerobic and Anaerobic transformations in Aquatic Sediment Systems	OECD 308
Direct Photolysis in Water (if wavelengths >290 nm are absorbed)	OPPTS 835.2210
Indirect Photolysis in Water	OPPTS 835.5270
Phototransformation of Chemicals on Soil Surfaces	OECD Jan. 2002 Draft
Simulation test-Aerobic Sewage Treatment (Activated Sludge Units)	OECD 303A
Anaerobic biodegradability of organic compounds in digested sludge	OECD 311
Fish Bioconcentration test	OPPTS 850.1730

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substances [

] (P-08-508) and [

] (P-08-509) ("the PMN substances") in the United States by DuPont Company ("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substances is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Company begins commercial manufacture of the PMN substances

for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substances solely for export in accordance with TSCA §12(a) and (b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substances for use in the United States, no further activity by the Company involving the PMN substances is exempt as "solely for export" even if some amount of the PMN substances is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substances while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substances that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

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

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

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substances when they are manufactured, pursuant to any of the exemptions in 40 CFR

720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(5) Imported Articles. The requirements of this Order do not apply to the PMN substances when they are imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(c) Automatic Sunset. If the Company has obtained for the PMN substances a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

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

PROHIBITION

The Company is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the PMN substances in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

TESTING

(a) Section 8(e) Reporting. Any information on the PMN substances which reasonably supports the conclusion that the PMN substances presents a substantial risk of injury to health or the environment required to be reported under EPA's section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978) as amended at 52 Federal Register 20083 (May 29, 1987), shall reference the appropriate PMN identification number for this substance and shall contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found in the reporting guide referenced at 56 Federal Register 28458 (June 20, 1991).

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Laboratory Data Integrity Branch (2225A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study;

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

(4) The appropriate PMN identification number for 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 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any such study, the Company must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (d) provide general guidance for development of test protocols, but are not themselves acceptable protocols. Approval of the test protocol does not mean pre-acceptance of test results. Because the Chronic Daphnid Toxicity study and the 90-day toxicity study enumerated below were begun before the execution of this Order the requirement for submission and approval of the protocols for these two studies only is waived.

(d) Triggered Testing Requirements. (i) The Company is prohibited from manufacturing or importing the PMN substances beyond the following aggregate manufacture and import volumes of both PMN substances combined ("the production limits"), unless the Company conducts the following studies and submits all final reports and underlying data in accordance with the conditions specified in this Testing section.

Production Limit	Study	Guideline
[ ] kilograms *	1) Repeated dose Metabolism and Pharmacokinetics rats and mice	OPPTS 870.7485
	2) Modified 1-generation Reproduction study	OECD 421, modified, per (iv) below

	3) Avian Reproduction-Bobwhite Quail	OPPTS 850.2300
	4) Fish Early Life Stage Toxicity	OPPTS 850.1400
	5) Daphnid Chronic Toxicity	OPPTS 850.1300

*An alternate Production Limit for studies 1 and 2 only is two years from the date of commencement of nonexempt commercial manufacture of either PMN substance, or [ ] kilograms, whichever comes later.

[ ] kilograms	6) 90-day toxicity study	OPPTS 870.3100 (OECD 408)
	7) Chronic toxicity/ carcinogenicity study	OPPTS 870.4300 (OECD 453)

(ii) the test substance shall be the substance described in P-08-509;

(iii) EPA recommends that the Company conduct the pharmacokinetics testing first to confirm species acceptability and to provide a reliable half-life for these substances;

(iv) The modifications for the 1-generation reproduction study (study 2 above) are: 1) increase the parental sample size to 20; 2) the duration of the study shall be extended to until the pups have reached sexual maturation; 3) parental males shall be dosed for 10 weeks prior to mating; 4) dosing of the parental animals shall be continued through lactation and then the pups should be directly dosed until they reach sexual maturation; 5) pup body weight shall be recorded on lactation days 0, 4, 7, 14, and 21 and then at weekly intervals; 6) litter size can be

standardized to 4 pups/litter on lactation day 4 (optional); 7) at weaning one pup/sex/litter shall be randomly selected to follow until sexual maturation; and 8) the time of sexual maturation shall be recorded (i.e. vaginal opening and preputial separation).

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data ("the report and data") to EPA no later than 14 weeks prior to exceeding the applicable production limit. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting", "Data and Reporting", and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will not require the submission of raw data such as slides and laboratory notebooks unless if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

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

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal,

the Company may continue to manufacture and import the PMN substances beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substances, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

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

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

(i) 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 substances beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

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

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e)(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 substances will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substances to mitigate exposures to or to better characterize the risks presented by the PMN substances. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, import, processing, distribution, use and disposal of the PMN substances, 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 substances in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substances.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI. of this Consent Order.

PROTECTION IN THE WORKPLACE

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

(1) General Dermal Protection. Each person who is reasonably likely to be dermally exposed in the work area to the PMN substances through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance

becomes airborne in a form listed in subparagraph (a)(5) of this section, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with Occupational Safety and Health Administration ("OSHA") dermal protection requirements at 29 CFR 1910.132, 1910.133, and 1910.138.

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

(i) Gloves.

(ii) Full body chemical protective clothing.

(iii) Chemical goggles or equivalent eye protection.

(iv) Clothing which covers any other exposed areas of the arms, legs and torso. Clothing in this subparagraph (a)(2)(iv) need not be tested or evaluated under the requirements of subparagraph (a)(3)

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

(i) Permeation Testing. Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the

chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area. Permeation testing shall be conducted according to the American Society for Testing and Materials ("ASTM") F739 "Standard Test Method for Resistance of Protective Clothing materials to Permeation by Liquids or Gases." Results shall be recorded as a cumulative permeation rate as a function of time (or versus time), and shall be documented in accordance with ASTM F739 using the format specified in ASTM F1194-99 "Guide for Documenting the Results of Chemical Permeation Testing on Protective Clothing Materials." Gloves may not be used for a time period longer than they are actually tested and must be replaced at the end of each work shift during which they are exposed to the PMN substances.

(ii) Manufacturer's Specifications. Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the PMN substances alone and in likely combination with other chemical substances in the work area.

(4) Respiratory Protection. Each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substance, P-08-508, in the form listed in subparagraph (a)(5) of this section, is provided with, and is required to wear, at a minimum, a NIOSH-certified respirator with an Applied Protection Factor ("APF") of 3000 from the respirators listed in subparagraph (a)(6) of this section. All respirators must be used in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. All respirators must be issued, used, and maintained according to an appropriate respiratory

protection program under the OSHA requirements in 29 CFR 1910.134.

In addition, each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substance P-08-509 must be provided with and wear an appropriate NIOSH-approved respirator.

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

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

(ii) Gas/vapor (all substances in the gas form), or

(iii) Combination Gas/Vapor and Particulate (gas and liquid/solid physical states are both present; a good example is paint spray mist, which contains both liquid droplets and vapor).

(6) Authorized Respirators. The following NIOSH-certified respirators meet the minimum requirements for P-08-508 in subparagraph (a)(4) of this section:

–a NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full face piece.

NEW CHEMICAL EXPOSURE LIMIT

(a) Alternative to Requirements of Respirator Section.

(1) EPA recommends and encourages the use of pollution prevention, source reduction, engineering controls and work practices, rather than respirators, as a means of controlling inhalation exposures whenever practicable.

(2) Whenever a person is reasonably likely to be exposed to the PMN substances by

inhalation, as an alternative to compliance with the respirator requirements in the Protection in the Workplace section of this Order, the Company may comply with the requirements of this New Chemical Exposure Limit section. However, before the Company may deviate from the respirator requirements in the Protection in the Workplace section of this Order, the Company must:

(i) submit to EPA a copy of the Company's sampling and analytical method for the PMN substances, verified in accordance with subsection (c)(3) of this New Chemical Exposure Limit section;

(ii) obtain exposure monitoring results in accordance with this New Chemical Exposure Limit section; and

(iii) based on those exposure monitoring results, select, provide, and ensure use if necessary of the appropriate respiratory protection specified in paragraph (e)(2) of this New Chemical Exposure Limit section by persons who are reasonably likely to be exposed to the PMN substances by inhalation.

(3) After appropriate respiratory protection has been selected at a workplace based on the results of actual exposure monitoring conducted in accordance with this New Chemical Exposure Limit section, the Company shall not, at that workplace, use the respiratory protection required in the Protection in the Workplace section of this Order (unless it is the same as required by this New Chemical Exposure Limit section).

(b) Exposure Limit.

(1) General. The following new chemical exposure limit ("NCEL") for the PMN

substances is an interim level determined by EPA based on the limited information available to the Agency at the time of development of this Order. The NCEL for the PMN substances is as follows:

(i) Time-Weighted Average ("TWA") Limit. The Company shall ensure that no person is exposed to an airborne concentration of both PMN substances combined in excess of 0.01 mg/m3 (the NCEL) as an 8-hour time-weighted average, without using a respirator in accordance with subsection (e) of this New Chemical Exposure Limit section.

(ii) Non-8-Hour Work-shifts. For non-8-hour work-shifts, the NCEL for that work-shift ("NCELn") shall be determined by the following equation: NCELn = NCEL x (8/n) x [(24-n)/16], where n = the number of hours in the actual work-shift.

(2) Automatic Sunset. If, subsequent to the effective date of this Order, OSHA promulgates, pursuant to §6 of the Occupational Safety and Health Act, 29 U.S.C. 655, a final chemical-specific permissible exposure limit ("PEL") specifically applicable to these PMN substances and the OSHA PEL is not challenged in court within 60 days of its promulgation, then any respirator requirements in the Protection in the Workplace section of this Order and any requirements of this New Chemical Exposure Limit section applicable to workers and situations subject to the OSHA PEL sball automatically become null and void. However, the requirements of this Consent Order are not negated by any pre-existing OSHA PEL applicable to the PMN substances.

(c) Performance-Criteria for Sampling and Analytical Method.

(1) Applicability. For initial development and validation of the sampling and analytical

method for the PMN substances, all the requirements of this subsection (c) apply. For subsequent exposure monitoring conducted pursuant to subsection (d) of this New Chemical Exposure Limit section, only the following requirements apply: (c)(4)(i), (4)(ii), (4)(iv)(II), (4)(v)(II), (8), (9), and (10). Any deviation from the requirements of this subsection (c) must be approved in writing by EPA.

(2) Submission of Verified Method and Certification Statement. The Company shall submit to EPA a copy of a validated sampling and analytical method for the PMN substances which satisfies the criteria specified in this subsection (c). The method description shall expressly state how the method compares with each quantitative requirement specified in this subsection (c). The submission must include a written statement, signed by authorized officials of both the Company and the Laboratory, certifying the truth and accuracy of the independent laboratory verification conducted pursuant to subsection (c)(3). To assist EPA in identifying the document, it shall state in a conspicuous, underlined subject-line at the top of the first page: "NCEL Sampling and Analytical Method for PMN # _____," after-which the correct PMN number for this chemical substance shall be stated.

(3) Verification of Analytical Method by Independent Third-Party Laboratory.

(i) Verification. The Company shall have an independent reference laboratory ("Laboratory") verify the validity of the analytical method for the PMN substances, in accordance with the other requirements in this subsection (c)(3). It is the Company's responsibility to ensure that the Laboratory complies with all the requirements specified in this subsection (c)(3).

(ii) Independent Reference Laboratory. The independent reference laboratory must be a separate and distinct person (as defined at 40 CFR 720.3(x)) from the Company and

from any other person who may have developed the method for the Company.

(iii) Accreditation. The Laboratory must be accredited by a formally recognized government or private laboratory accreditation program for chemical testing and/or analysis.

(iv) Good Laboratory Practice Standards. The Laboratory verification of the analytical method for the PMN substances must comply with TSCA Good Laboratory Practice Standards ("GLPS") at 40 CFR Part 792. (Certain provisions of the TSCA GLPS applicable to toxicity testing in laboratory animals, such as 40 CFR 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are clearly inapplicable to the NCEL requirements.) However, compliance with TSCA GLPS is not required under this New Chemical Exposure Limit section where the analytical method is verified by a laboratory accredited by either: (A) the American Industrial Hygiene Association ("AIHA") Industrial Hygiene Laboratory Accreditation Program ("IHLAP"); or (B) another comparable program approved in advance in writing by EPA.

(v) Analysis of Duplicate Samples. The Company shall collect six duplicate samples (a total of 12) at the TWA concentration. The samples shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substances onto a sample collection device. The duplicate samples shall be collected on identical collection media, at the same time, and under the same conditions. One set of six samples shall immediately be analyzed by the Company, the other set of six samples shall be analyzed by the Laboratory using the method developed by or for the Company.

(vi) Sample Storage Study. If the results of the analysis of duplicate samples

pursuant to paragraph (c)(3)(v) do not satisfy the requirements in paragraph (c)(3)(vii), the Company must perform a sample storage study as follows:

(I) Triplicate Samples. The Company shall collect six triplicate samples (a total of 18) at the TWA concentration. The samples shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substances onto a sample collection device. The triplicate samples shall be collected on identical collection media, at the same time, and under the same conditions. One set of six samples shall immediately be analyzed by the Company.

(II) Analysis After Sample Storage. A sample storage evaluation shall be performed with the two remaining sets of six samples. One set of six samples shall be analyzed by the Laboratory using the method developed by or for the Company, and the other shall be analyzed by the Company on the same day as the Laboratory analyzes its six samples. Specialized storage conditions for the samples including extraction conditions, time from sampling to extraction, time from collection or extraction (if applicable) to analysis and storage conditions must be specified in the method description.

(vii) Comparison of Results. The difference between the results of the two sets of six samples analyzed by the Laboratory and the Company as required in either paragraph (c)(3)(v) or (c)(3)(vi)(II) shall be evaluated using a two-sample t-test with unequal variances, and the two sides of the critical regions shall not exceed a 5% significance level. (See Attachment B - Statistical Analysis of NCELs Analytical Method Verification Results.) The arithmetic mean of each set of six samples must be within 10% of the overall arithmetic mean of the two sets of

sample measurements. If the arithmetic mean of each set of six samples is not within 10% of the overall arithmetic mean, then the sample storage time between collection and analysis must be reduced until the average of each set of six samples is within 10% of the overall arithmetic mean.

(4) Accuracy. The sampling and analytical method must clearly demonstrate the following:

(i) General. The sampling and analytical method, and all exposure monitoring data relied on by the Company, shall be accurate to within ±25% at a 95% confidence level for concentrations of the PMN substances ranging from one half the NCEL to twice the NCEL.

(ii) NCEL Quantitation Limits. The analytical method should be capable of reliably quantifying the PMN substances across the full range of reasonably likely exposures. At a minimum, the analytical method must be capable of reliably quantifying from a lower quantitation limit ("LQL") of one half the NCEL to an upper quantitation limit ("UQL") of at least twice the NCEL. If the Company obtains an exposure monitoring sample that is more than 10% above the actual UQL of the analytical method, the Company must comply with paragraph (e)(4)(i).

(iii) Lower Quantitation Limit Signal-To-Noise Ratio. The analytical method shall be capable of quantifying the PMN to a concentration of one half the NCEL with a signal that is at least five times the baseline noise level. Baseline noise must be amplified to a measurable level when possible, even if the required amplification is beyond that used in routine analysis of samples. (If baseline noise cannot be obtained, another reference must be selected. This may be a peak considered to be noise caused by the reagent matrix.) The sampling preparation method must be specified and the detection limit for the analytical procedure must be

reported as mass per injection for chromatographic techniques.

(iv) Instrument Calibration.

(I) Initial Calibration. For method development and validation (but not subsequent exposure monitoring), the initial calibration shall at a minimum consist of five (5) calibration standards with a linear correlation of 0.95 -- these five (5) calibration standards must consist of one standard at each of the following concentrations: one half the NCEL (0.5 x NCEL); between one half and one times the NCEL (0.5 x NCEL < > 1 x NCEL); one times the NCEL (1 x NCEL); between one and two times the NCEL (1 x NCEL < > 2 x NCEL), and twice the NCEL (2 x NCEL).

(II) Continuing Calibration. During each week of both method development/validation and subsequent exposure monitoring, the Company shall conduct both an initial instrument calibration and a continuing calibration. The Company shall perform at least one continuing calibration sample at the NCEL concentration, and at least one additional calibration sample per every 10 samples analyzed. The continuing calibration sample shall fall within $\pm$ 25% of the initial calibration value. If not, then the initial calibration must be repeated, and any samples associated with that outlying calibration check must be re-analyzed.

(v) Calculated Percent Recovery.

(I) Initial Calculation. For method development and validation, the Company must calculate the percent of the PMN substances recovered by the analytical method from a sample containing a known quantity of the PMN substances. The sample shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor

pressure, by injecting the PMN substances onto a sample collection device. (Such a sample is referred to as a "matrix spike"). The calculated percent recovery for each matrix spike shall be greater than or equal to 75% and less than or equal to 125%. Spike concentrations for the PMN substances must be included in the sampling and analytical method submitted to EPA.

(II) Subsequent Calculation. During each subsequent exposure monitoring episode or campaign, at least 1 matrix spike, prepared by injecting the PMN substances onto a sample collection device, shall be analyzed. (This matrix spike must be prepared at the NCEL concentration.)

(vi) Sampling Device Capacity. The capacity of the sampling device must be tested and results reported to show under a known and well-defined set of conditions that the device is capable of collecting the new chemical in solid, liquid or vapor phase with minimal loss. The sampling device's capacity (air volume and collected analyte mass) must be specified. For methods that use adsorbent tubes as the collection medium, evidence of the capacity must be provided in the form of breakthrough testing. This testing must be done at a concentration twice the NCEL and under conditions similar to those expected in the workplace. Breakthrough is defined to have occurred when the concentration of the PMN substances in the effluent stream is equal to 5% of the concentration of the influent stream, or when 20% of the PMN substances is detected in the backup section of the sampler.

(vii) Sampling Device Desorption Efficiency. Where applicable, the desorption efficiency must be evaluated for the air sampling device. A minimum of six air samples spiked with the PMN substances at least the NCEL concentration must be prepared. A recovery of at least 75% must be obtained for each of the six samples.

(5) Precision. The estimate of the coefficient of variation of each set of six samples from the controlled atmosphere test (spiked at 1.0 NCEL, per paragraphs (c)(3)(v) or (vi)) must be less than 0.105, including allowance of 0.05 for error due to sampling.

(6) Interpretation of Accuracy and Precision Data.

(i) If a single matrix spike recovery is less than 75% recovery or greater than 125% or the estimated coefficient of variation is greater than 0.105, then the Company must re-prepare the matrix spike, re-sample, and re-analyze all samples associated with such matrix spike or triplicate samples.

(ii) For percent recoveries less than 90% but greater than 75%, correction for low recovery is required. Correct for recovery first by dividing the observed amount by the proportion recovered before determining if measurements fall below the NCEL. For example, if the observed level is 30 mg/m^3 and the percent recovery is 75%, use the value 30 $mg/m^3/(0.75)$ = 40 mg/m^3 when determining whether the levels are below the exposure limit.

(7) Representativeness. All sample conditions used to develop the methodology shall mimic the actual workplace environment expected to be monitored. Conditions such as the temperature, humidity, lighting, and presence of other chemicals, etc. must mimic the conditions in the workplace to be monitored.

(8) Changes Affecting Validity. If the workplace environment changes from the initial conditions described in the verified sampling and analytical method in a way reasonably likely to invalidate the accuracy of the method, then the Company must comply with the respirator requirements in the Protection in the Workplace section of this Order, unless the Company re-validates the method to confirm that the requirements for accuracy and precision in paragraphs

(c)(4) and (5) are met. Examples of possible changes include but are not limited to: introduction of a new chemical substance to the workplace which may interfere with the analysis of the new chemical; introduction of light to the workplace which may interfere with light-sensitive PMN substances; or introduction of water/increased humidity to the workplace which could react with the PMN substances and cause difficulties in collection and analysis.

(9) Comparability. All data and results shall be reported in the same units of measurement as the NCEL.

(10) Responsibility for Method Validity. The independent laboratory verification and EPA receipt of the sampling and analytical method pursuant to this subsection (c) do not ensure that the method will produce valid exposure monitoring data. The Company is ultimately responsible for ensuring the validity of its exposure monitoring data.

(d) Monitoring Potential Exposure.

(1) General.

(i) Action Level. The "action level" is defined as an airborne concentration of the PMN substances, calculated as an 8-hour time-weighted average, equal to one half the NCEL TWA specified in subparagraph (b)(1). For non-8-hour work shifts, the action level is equal to one half the NCELn. (The NCELn is described in subparagraph (b)(1)(ii).) The Company may exceed the action level without penalty. The purpose of the action level is solely to determine the requisite monitoring frequency.

(ii) Representative Exposure Groups. Whenever exposure monitoring is required by this New Chemical Exposure Limit section, the Company shall take representative samples of

what the potential exposure of each person who is reasonably likely to be exposed to airborne concentrations of the PMN substances would be if respirators were not worn. The Company shall do so by sampling the breathing zone air of at least one person that represents, and does not underestimate, the potential exposure of every person performing the same or substantially similar operations in each work shift, in each job classification, in each work area (hereinafter identified as an "exposure group") where inhalation exposure to the PMN substances is reasonably likely to occur. The exposure of each person need not be itself directly sampled if that exposure is represented by sampling the exposure of another person in the same exposure group.

(iii) Good Laboratory Practice Standards. Determinations of potential inhalation exposure shall be made according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and the sampling and analytical method developed pursuant to subsection (c) of this New Chemical Exposure Limit section. [Certain provisions of the TSCA GLPS applicable to toxicity testing in laboratory animals, such as 40 CFR 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are clearly inapplicable to the NCEL requirements.] However, compliance with TSCA GLPS is not required where exposure monitoring samples are analyzed by a laboratory accredited by either: (A) the American Industrial Hygiene Association ("AIHA") Industrial Hygiene Laboratory Accreditation Program ("IHLAP"); or (B) another comparable program approved in advance in writing by EPA.

(iv) Full Shift Exposure Samples. Representative 8-hour TWA airborne concentrations shall be determined on the basis of samples representing the full shift exposure for

each exposure group.

(2) Initial Monitoring. Before the Company may deviate from the respirator requirements of the Protection in the Workplace section, the Company shall conduct initial exposure monitoring to accurately determine the airborne concentration of the PMN substances for each exposure group in which persons are reasonably likely to be exposed to the PMN substances.

(3) Periodic Monitoring.

(i) If any representative samples taken during the initial exposure monitoring reveal an airborne concentration at or above the action level but at or below the TWA, the Company shall repeat the exposure monitoring for that exposure group at least every 6 months. If the PMN substances are not manufactured, processed, or used at all during a given 6 month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the PMN substances is resumed. However, cessation of manufacturing, processing and use of the PMN substances for less than the 6 month period does not constitute grounds for postponement of the 6 month deadline to conduct exposure monitoring.

(ii) If any representative samples taken during the initial exposure monitoring reveal an airborne concentration above the TWA, the Company shall repeat the exposure monitoring for that exposure group at least every 3 months. If the PMN substances are not manufactured, processed, or used at all during a given 3 month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the PMN substances is resumed. However, cessation of manufacturing, processing and use of the PMN substances for less than the 3 month period does not constitute grounds for postponement of the

3 month deadline to conduct exposure monitoring.

(iii) The Company may alter the exposure monitoring schedule from every 3 months to every 6 months for any exposure group for whom two consecutive measurements taken at least 7 days apart indicate that the potential exposure has decreased to the TWA or below, but is at or above the action level. Where the PMN substances are manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(4) Termination of Monitoring.

(i) If representative samples taken during the initial exposure monitoring reveal an airborne concentration below the action level, the Company may discontinue monitoring for that exposure group, except when additional exposure monitoring is required by paragraph (d)(5) of this New Chemical Exposure Limit section.

(ii) If representative samples taken during the periodic monitoring reveal that an airborne concentration, as indicated by at least 2 consecutive measurements taken at least 7 days apart, are below the action level, the Company may discontinue the monitoring for that exposure group, except when additional monitoring is required by paragraph (d)(5) of this New Chemical Exposure Limit section. Where the PMN substances are manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(5) Additional Monitoring.

(i) For a previously monitored exposure group, the Company shall, within 7 days of any of the events listed below in this paragraph (d)(5)(i), conduct the initial exposure monitoring followed by any periodic or additional exposure monitoring required by subsection (d) of this New Chemical Exposure Limit section:

(I) change in the production volume, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the PMN substances;

(II) spills, leaks, ruptures or other breakdowns occur that may reasonably cause new or additional exposures to the PMN substances; and

(III) whenever else the Company has any reason to suspect a change that may reasonably result in new or additional exposures to the PMN substances.

(ii) In no event is the additional exposure monitoring requirement in paragraph (d)(5)(i) intended to delay implementation of any necessary cleanup or other remedial action. During any cleanup or remedial operations that may occur before commencing additional exposure monitoring, the Company shall ensure that potentially exposed persons use at least the respiratory protection specified in subsection (e) for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

(6) Notification of Monitoring Results.

(i) Within 15 working days after receipt of the results of any exposure monitoring required by this Order, the Company shall notify each person whose exposure is represented by that monitoring. The notice shall identify the NCEL, the exposure monitoring results, and any

corresponding respiratory protection required by subsection (e). Affected persons shall be notified in writing either individually or by posting the information in an appropriate and accessible location.

(ii) Whenever the NCEL is exceeded, the written notification required by the preceding paragraph shall describe the action being taken by the Company to reduce inhalation exposure to or below the NCEL, or shall refer to a document available to the person which states the actions to be taken to reduce exposure.

(7) Exemption based on Objective Data. Where the Company has documented and reliable objective data demonstrating that, even under worst-case conditions, employee exposure to the PMN substances will not exceed the action level (defined in paragraph (d)(1)(i)) under the expected handling procedures and conditions for a specific "exposure group" (defined in paragraph (d)(1)(ii)), then that exposure group is exempt from this New Chemical Exposure Limit section (except paragraph (d)(5) "Additional Monitoring" and subsection (f) "NCEL Record-keeping") and the respirator requirements in the Protection in the Workplace section of this Order. Any such objective data must accurately characterize actual employee exposures to the PMN substances and must be obtained under conditions closely resembling the types of materials, processes, control methods, work practices, and environmental conditions in the Company's current workplace operations with the PMN substances. Examples of objective data that may be used to demonstrate that employee exposure will not exceed the action level, even under worst case conditions, include information on the physical and chemical properties of the PMN substances, industry-wide studies, and/or laboratory test results.

(e) Respiratory Protection.

(1) General. Whenever the Company has conducted exposure monitoring at a workplace in accordance with subsection (d) of this New Chemical Exposure Limit section and the measured airborne concentration of the PMN substances for any person who is reasonably likely to be exposed to the PMN substances by inhalation exceeds the NCEL, the Company shall provide those persons the respirators specified in this subsection (e) (rather than the respirator(s) identified in the Protection in the Workplace section of this Order), and shall ensure that the respirators are used (including training, fit testing, and maintenance) in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. When the Company has not yet measured the airborne concentration of the PMN substances at a workplace in accordance with this New Chemical Exposure Limit section, the Company shall comply with the respirator requirements in the Protection in the Workplace section of this Order at that workplace.

(2) Selection of Appropriate Respiratory Protection. After the Company has conducted exposure monitoring in accordance with subsection (d) of this New Chemical Exposure Limit section, the Company shall select, provide, and ensure that persons who are reasonably likely to be exposed to the PMN substances by inhalation use, at a minimum, the respiratory protection which corresponds in the following table to the measured airborne concentration (or a more protective respirator which corresponds to a concentration higher than measured)

Measured Concentration of PMN Substance	**Required Respiratory Protection**

≤ NCEL	-- No respiratory protection is required.
≤ 10 x NCEL	*If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:* -- NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). -- NIOSH-certified powered air-purifying respirator equipped with a loose fitting hood or helmet and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).
≤ 25 x NCEL	*If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:* -- NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). -- NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).
≤ 50 x NCEL	*If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:* -- NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific). *If No Cartridge Service Life Testing is Available:* -- NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting full facepiece.
≤ 2000 x NCEL	-- NIOSH-certified supplied-air respirator operated in pressure demand or

	other positive pressure mode and equipped with a tight-fitting full facepiece.
> 2000 x NCEL	-- Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode.
	-- Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode.

(3) Reductions in Respiratory Protection. After appropriate respiratory protection has been selected based on the results of actual exposure monitoring conducted at a workplace in accordance with subsection (d) of this New Chemical Exposure Limit section, the Company shall not, at that workplace, use the respiratory protection required by the Protection in the Workplace section of this Order (unless it is the same as required by this New Chemical Exposure Limit section). Before the Company may make any reduction in any respiratory protection selected pursuant to this New Chemical Exposure Limit section, the Company must verify, by 2 consecutive measurements taken at least 7 days apart, that the new respiratory protection is appropriate in accordance with paragraph (e)(2). Where the PMN substances is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(4) Special Situations.

(i) Measurements Outside Quantitation Limits. When a value less than the lower quantitation limit ("LQL") of the analytical method (as described in paragraph (c)(4)(ii)) is

measured, the Company shall estimate potential exposure using generally established and accepted statistical methods. If the Company obtains an exposure monitoring sample that is more than 10% above the actual upper quantitation limit ("UQL") of the analytical method, the Company must ensure that its workers wear at least a NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece. Any reductions in this respiratory protection must comply with paragraph (e)(3). The Company may submit an improved analytical method provided that it complies fully with subsection (c) of this New Chemical Exposure Limit section, including the verification required by subsection (c)(3).

(ii) Cleanup and Remedial Actions. During any special cleanup or other remedial actions that may occur before commencing additional exposure monitoring (as discussed in paragraph (d)(5)(ii)), the Company shall ensure that potentially exposed persons use at least the respiratory protection specified above in this subsection (e) for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

(f) NCEL Recordkeeping.

(1) Whenever the Company elects to comply with this New Chemical Exposure Limit section rather than the respirator requirements in the Protection in the Workplace section of this Order, the Company shall maintain the following records until 30 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:

(i) A copy of the sampling and analytical methods used and continuing evidence

of their accuracy over time as required by section (c);

(ii) Records documenting compliance with the analytical method verification requirements of subsection (c)(3), including copies of the signed certification statement and the verification results obtained by both laboratories;

(iii) Records documenting either compliance with the Good Laboratory Practice Standards at 40 CFR Part 792, or use of a laboratory accredited by the American Industrial Hygiene Association ("AIHA") or another comparable program approved in advance in writing by EPA. Where the Company elects to not comply with TSCA GLPS, such records shall include the written accreditation from the AIHA or the written approval from EPA.

(iv) Records documenting all exposure monitoring dates, duration, and results of each sample taken;

(v) Records documenting the name, address, work shift, job classification, and work area of the person monitored and of all other persons whose exposures the monitoring is intended to represent;

(vi) Any conditions that might have affected the monitoring results;

(vii) Notification of exposure monitoring results required by paragraph (d)(6);

(viii) Records documenting any changes in the production, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the PMN substances;

(ix) Records documenting any spills, leaks, ruptures or other breakdowns that may cause new or additional exposure;

(x) The type of respiratory protective devices worn by the monitored person, if any;

(xi) Records documenting any actions taken to mitigate exposures to the PMN substances;

(xii) Records documenting reliance on the objective data exemption in paragraph (d)(7), including: (A) the source of the data, (B) protocols and results of any relevant testing or analysis, (C) a description of the operation exempted and how the data demonstrate that employee exposures will not exceed the action level, (D) other data relevant to the operations, materials and employee exposures covered by the exemption.

MANUFACTURING

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

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substances under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substances and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substances of the existence of the SNUR.

CONTROL OF EFFLUENT & EMISSIONS

(a) The Company shall recover and capture (destroy) or recycle the PMN substances at an overall efficiency of 99% from all the effluent process streams and the air emissions (point source and fugitive).

DISTRIBUTION

(a) Distribution Requirements. Except as provided in paragraph (b), the Company shall distribute the PMN substances outside the Company, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Comply with the same requirements and restrictions, if any, required of the Company in the Protection in the Workplace and the New Chemical Exposure Limit sections of this Order;

(2) Distribute the PMN substances only to a person who will either recover and capture (destroy) or recycle the PMN substances from all effluent process streams and air emissions (point source and fugitive) at an overall efficiency of 99%; and

(3) Distribute the PMN substance P-08-509 in an aqueous dispersion of the polymer product or on a heat treated solid product such that the contents polymer residual P-08-508/509 cumulative total [ ] are below 200 ppb level using the ASE method developed by Larsen et al[1] with the level of quantification (LOQ) for the standard solution at 0.5 ppb. If non-heat treated solid polymer is distributed by the Company, such person shall not further distribute until heat treatment is performed at temperature and residence time sufficient to produce a product with P08-508/509 cumulative residual levels equivalent to the heat treated

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[1]Larsen et al, "Efficient "total" extraction of perfluorooctanoate from polytetrafluoroethylene fluoropolymer", *Analyst*, 2006, 131, 1105-1108.

polymer distributed by the Company, (i.e., below 200 ppb).

(b) Temporary Transport and Storage. Notwithstanding paragraph (a), the Company may distribute the PMN substances outside the Company for temporary transport and storage in sealed containers provided the following two conditions are met:

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

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substances may occur only while the PMN substances 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 substances, 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 substances (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 substances 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 substances 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 substances without submitting a significant new use notice to EPA, the Company shall cease supplying the PMN substances to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substances 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 substances under section 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, 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 substances 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 substances of the existence of the SNUR. Such

notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substances. Such notice must also reference the publication of the SNUR for this PMN substances 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 substances, then the Company is not required to obtain from such persons the written agreement specified in paragraph (a).

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substances did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substances eligible for the Export exemption in Section I, Paragraph (b)(3) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substances eligible for the Research and Development exemption in Section I, Paragraph (b)(2) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for

5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substances claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture and importation volume of the PMN substances and the corresponding dates of manufacture and import;

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

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

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

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

(7) Records required by paragraph (f). of the New Chemical Exposure Limits section of this Order, if applicable;

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

(9) Records documenting compliance with the Control of Effluent & Emissions section of this Order;

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

(11) The Company shall keep a copy of this Order at each of its sites where the PMN substances are manufactured or imported.

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget (OMB), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Orders has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may ocassionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substances. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such

inspections. Such requests may be written or oral. The types of information that EPA may request may include, but are not limited to, the following:

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

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

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

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

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

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

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable to the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of

TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substances, including the right to manufacture the PMN substances, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substances from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture or import of the PMN substances.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit a new PMN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substances, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full

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

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substances, including the right to manufacture the PMN substances, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment C to this Order.

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

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substances is manufactured or imported. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN substances under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

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

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substances pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substances manufactured and imported by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health effects of, or human exposure to, the PMN substances, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substances and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke 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 substances.

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

VII. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to, the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

1/26/09
Date

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

1/28/09
Date

/s/
Name: James R. Hoover

Title: Global Regulatory Manager

Company: DuPont 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 labelled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

STATISTICAL ANALYSIS OF NCELs ANALYTICAL METHOD VERIFICATION RESULTS

This Attachment describes the statistical technique (with examples) for comparing the analytical results obtained by two laboratories pursuant to paragraph (c)(3)(vii) of the New Chemical Exposure Limit section of this Order.

STATISTICAL TECHNIQUE

To obtain two-sample t test with unequal variances, perform the following operations:

- Compute means of the data measured by two laboratories.
- Compute mean squares

$$S_i^2 = \sum(\bar{X}_{ij} - X_i)^2/(n_i - 1),\ i=1, 2$$

- Form the ratio

$$T = (\bar{X}_1 - \bar{X}_2)/(W_1 + W_2)^{1/2}$$

- Compute degrees of freedom

$$f = (W_1 + W_2)^2/[W_1^2/(n_1 - 1) + W_2^2/(n_2 - 1)]$$

where,

$W_1 = S_1^2/n_1,\ i = 1, 2$

$\bar{X}_1$ = Average of the results from the company laboratory

$\bar{X}_2$ = Average of the results from the independent laboratory

n_1 = Number of samples analyzed by the company laboratory

n_2 = Number of samples analyzed by the independent laboratory.

Then compare the absolute value of T to the 97.5 percentile point of a t distribution with f degrees of freedom. If the absolute value exceeds the 97.5 percentile point, the results measured

by two laboratories are significantly different at 95% level. Otherwise, they are not significantly different. In general, f may not be a integer. Use interpolation to obtain the 97.5 percentile point of a t distribution with f degrees of freedom.

EXAMPLES -- The following examples (based on simulated data) illustrate the method:

Example 1

Data Set 1	Data Set 2
80.56	97.11
100.01	102.13
86.04	99.83
52.61	97.83
84.85	105.44
95.75	100.04

$\overline{X}_1 = 83.30$ $n_1 = 6$ $\overline{X}_2 = 100.40$ $n_2 = 6$

$S_1^1 = 278.72$ $W_1 = 46.25$ $S_2^2 = 9.26$ $W_2 = 1.54$

Absolute value of T = 2.467 f = 5.33

The t table shows that the 97.5 percentile point is 2.571 and 2.447 for 5 and 6 degrees of freedom, respectively. For 5.33 degrees of freedom, the 97.5 percentile point will be approximately 2.530 which is greater than the absolute value of T, 2.467. Hence, the means of two data sets are not significantly different at the 5% level.

However, if this problem had been treated as an ordinary two-sample t test, the means would be significantly different at the 5% level because the absolute of T is greater than 2.228, the 97.5 percentile point for the t distribution with 10 degrees of freedom.

Example 2

Data Set 1	Data Set 2
82.87	108.05
101.85	96.51
87.44	100.04
99.68	104.33
101.15	110.32
99.21	107.00

$\overline{X}_1 = 95.37$ $n_1 = 6$ $\overline{X}_2 =$ 104.37 $n_2 = 6$

$S_1^1 = 65.59$ $W_1 = 10.93$ $S_2^2 = 27.25$ $W_2 = 4.54$

Absolute value of T = 2.290 f = 8.54

The t table shows that for 8 and 9 degrees of freedom the 97.5 percentile point is 2.306 and 2.262, respectively. For 8.54 degrees of freedom the 97.5 percentile point will be approximately 2.282 which is less than the absolute value of T, 2.290. Hence, the means of two data sets are significantly different at the 5% level.

ATTACHMENT C

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

_____ _____
Company (Transferor) PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice ("PMN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substances Control Act (TSCA, 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

____ reasserts,

____ relinquishes, or

____ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

Company (Transferor)	PMN Number
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Successor in Interest	
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Address	
City, State, Zip Code	

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

_____
Successor's Technical Contact

_____
Address

_____
City, State, Zip Code

_____
Phone