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7/30/03

9/27/03

tk 11/16/17

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice
	)	Number:
	)	
	)	
	)	
	)	
	)	
3M Company	)	P-03-77
	)	
	)	
	)	
	)	
	)	

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 notice ("PMN") P-03-77 submitted by 3M Company ("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMN to EPA pursuant to section 5(a)(1) of TSCA and 40 CFR Part 720.

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

II. SUMMARY OF TERMS OF THE ORDER

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

(a) provide risk notification in a Material Safety Data Sheet if test data indicate that the PMN substance may present a risk to human health or the environment;

(b) take additional precautionary actions if deemed necessary by EPA; and

(c) maintain certain records.

III. CONTENTS OF PMN

Confidential Business Information Claims (Bracketed in the Preamble and Order): production volume, manufacture, processing, and use information, other information.

Chemical Identity:

phosphonium, tributyl (2-methoxypropyl)-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-1-butanesulfonamide (1:1).

Use: Cure catalyst

Maximum 12-Month Production Volume: [ ] kilograms per year.

Test Data Submitted with PMN:

Oral two-generation reproduction study in rats, LD0 = 2000 mg/kg
Aquatic invertebrate acute toxicity test, freshwater daphnids, 4.8 ppm
Fish acute aquatic toxicity test, 49.0 ppm; and
Algal toxicity study, 7.6 ppm.

IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

The following are EPA's predictions regarding the probable toxicity, human exposure and environmental release of the PMN substance, based on the information currently available to the Agency.

Human Health and Environmental Effects Summary:

EPA has concern for liver toxicity, irritation to mucous membranes, lungs, and eyes based on Agency analogue data. There is also potential concern for developmental and reproductive effects for the anion by analogy to which has a NOEL of 0.1 mg/kg in an oral 2-generation reproduction study in rats. Based on test data summaries on the PMN substance and Structure Activity Relationship (SAR) analysis based on

analogy to cationic surfactants (see www.epa.gov/oppt/newchems/chemcat.htm), there is potential concern for toxicity to aquatic organisms.

EPA also has significant concern for potential degradation products, byproducts, unreacted material, and low molecular weight species. The PMN is a derivative of

Concerns for the PMN substance are based on analogy of

is currently under review by EPA for persistence, bioaccumulation, and toxicity (PBT) concerns. Studies indicate that human and animal exposures to are widespread and that bioaccumulates. It has been found at very low levels in the blood of the general human population as well as in wildlife. The mechanism for bioaccumulation and exposure is not yet known. Toxicity studies on indicate developmental, reproductive and systemic toxicity in various species. These factors, taken together, raise concerns for potential adverse chronic effects in humans and wildlife if should continue to be produced, released, and built up in the environment.

EPA does not have comparable toxicity information on the PMN substance (and possible degradation products, byproducts, unreacted starting material and low molecular weight species). A pharmacokinetics study on in the Cynomolgus Monkey was submitted with a prenotice communication for related -derived substances. This study indicates that the half-life of in the body is less than 24 hours, whereas the half-life of in the body is greater than two years, according to information available to EPA at the time of its review.

Although pharmacokinetics data support reduced bioaccumulation, relative to the PMN substance is, nevertheless, expected to be persistent (see in the Environment: Sources, Dispersion, Fate, and Effects. 3M. St. Paul, MN. March 1, 2000), and mobile in the environment. Currently, EPA lacks adequate information to evaluate the human and environmental effects of the PMN substance. Because of a specific concern for and a general concern for and because there is significant uncertainty about the human and environmental toxicity and environmental fate of the PMN substance and EPA concludes that long term exposure to the PMN substance may present an unreasonable risk to human health and the environment.

On May 2, 2002, EPA entered into a Consent Order with 3M Company which requires 3M to submit test data on a structurally analogous chemical, Testing on is listed in the preamble of the Order on as a condition of modification or revocation of that Order. The test data on should provide information that furthers the understanding of the test results for P-03-77. Additional testing on P-03-77 may be required if the results for indicate areas of 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 substance. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of

TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substance.

B. In light of the potential risk of human health and environmental effects posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance, and the Agency's conclusion that issuing the Order will not result in any significant loss of benefits to society, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health and the environment.

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

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

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

Because concerns for the PMN substance are based on analogy between

, and because is a potential degradation product of the PMN substance, the testing for included in the preamble of the Consent Order for (an analogous chemical substance previously submitted by the Company), is necessary to evaluate the human health and environmental effects which may be caused by this PMN substance. Many of the studies included in the preamble of the Consent Order for have already been submitted to the Agency. The following studies have not yet been submitted and reviewed by EPA:

Health Toxicity Testing on	**OECD Guideline**	**OPPTS Guideline**
90-day oral toxicity - rodent	408	870.3100
Reproduction and fertility effects (Two generation reproduction toxicity)	416	870.3800
Combined chronic toxicity/carcinogenicity (need for this depends on results of previous studies)	453	870.4300

Ecotoxicity and Fate Testing on _____	**OECD Guideline**	**OPPTS Guideline**
Indirect Photolysis screening test: Sunlight photolysis in waters containing dissolved humic substances		835.5270
Avian reproduction test	206	850.2300

Due to the limited water solubility of these substances and consequent analytical difficulties, some modification of the protocols may be necessary. These modifications will be agreed upon between EPA and the Company.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CONSENT ORDER

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

3M Company ("the Company") is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the chemical substance phosphonium, tributyl (2-methoxypropyl)-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-1- butanesulfonamide (1:1) (P-03-77) ("the PMN substance") in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except under the following conditions:

MANUFACTURING

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

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

(3) When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations.

RISK INFORMATION

(a) Any information on the PMN substance which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or the environment required to be reported under EPA's section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978) as amended at 52 Federal Register 20083 (May 29, 1987), shall reference the appropriate

PMN identification number for this substance and shall contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found in the reporting guide referenced at 56 Federal Register 28458 (June 20, 1991).

(b) (1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, import, processing, distribution, use and disposal of the PMN substance, unless either:

(2) within 2 weeks from receipt of the notice described in subparagraph (b)(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 (b)(1), the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, import, process, distribute, use and dispose of the PMN substance in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of

receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substance.

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Order or related Orders, the Company becomes aware that the PMN substance may present a risk of injury to human health or the environment (or is so notified by EPA), the Company must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet ("MSDS") within 90 days from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured, imported, processed, or used in the Company's workplace, the Company must add the new information to an MSDS before the PMN substance is reintroduced into the workplace.

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

II. RECORDKEEPING

(a) 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:

A. RECORDS

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

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

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

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

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

B. APPLICABILITY

The provisions of this Recordkeeping Section are applicable only to activities of the Company 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 section 5(e) Consent Order has been approved under currently valid OMB Control Number 2070-0012.

III. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

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

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

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

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

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

(1) "Successor in Interest" means a person outside the Company who has acquired the

Company's full interest in the rights to manufacture the PMN substance, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(3).

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

(d) Notices.

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

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

(3) Transfer Document. Copies of the Transfer Document must be maintained by the

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

(e) Liability.

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

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

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

IV. MODIFICATION AND REVOCATION OF CONSENT ORDER

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

risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

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

V. EFFECT OF CONSENT ORDER

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

6/19/03
Date

for Philip S. Oshida, Acting Director
Chemical Control Division
Office of Pollution Prevention
and Toxics

7/14/03
Date

ATTACHMENT A

DEFINITIONS

"Company" means the person or persons subject to this Order.

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

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

"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.

ATTACHMENT B

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

_____ P03-77
Company (Transferor) PMN Number

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

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

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

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information (CBI) claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer.

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

P03-77
PMN Number

Company (Transferor)

Signature of Authorized Official

Date

Printed Name of Authorized Official

Title of Authorized Official

Successor in Interest

Signature of Authorized Official

Date

Printed Name of Authorized Official

Title of Authorized Official

Address

City, State, Zip Code

Successor's Technical Contact

Address

City, State, Zip Code

Phone