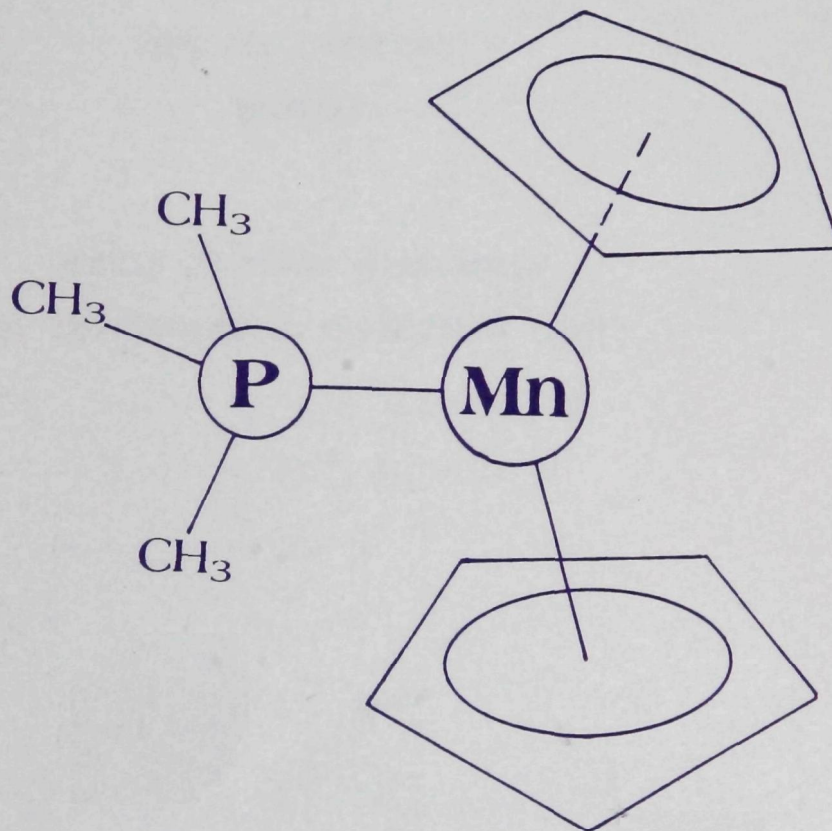




# Chemical Control in the United States:

## Accomplishments Under the New Chemical Program



CHEMICAL CONTROL IN THE UNITED STATES:  
\\  
ACCOMPLISHMENTS UNDER  
THE NEW CHEMICAL  
PROGRAM

OFFICE OF TOXIC SUBSTANCES  
U.S. ENVIRONMENTAL PROTECTION AGENCY

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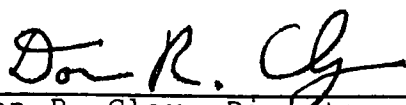
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## INTRODUCTION

In recent years, many nations have instituted programs to review the hazards presented by chemical substances before they are introduced into commerce. Under these programs the hazards of such chemicals can be controlled before harm to human health or the environment occurs.

These national programs have been assisted in their development by the work of the Organization for Economic Co-operation and Development (OECD) which has conducted an active program in promoting common approaches to chemical control within member nations. Among the objectives of the OECD Chemicals Program is the exchange of information and experience gained in the implementation of national programs.

This report provides the second annual summary of actions taken under the United States New Chemical Program, which is mandated by the Toxic Substances Control Act (TSCA). EPA believes that the dissemination of such information internationally will assist in developing better understanding of the U.S. New Chemical Program and may be of use to other nations involved in similar programs.

  
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Don R. Clay, Director  
Office of Toxic Substances

## PREFACE

In authorizing the Toxic Substances Control Act (TSCA), (15 USC 2601 et seq.), Congress recognized that health and environmental risks are more easily addressed before, rather than after, a chemical is manufactured and introduced into commerce. Section 5 of TSCA authorizes the Environmental Protection Agency (EPA) to review new chemicals prior to manufacture or import for potential human health and environmental effects and, if necessary, regulate the chemicals to limit any unreasonable risks which they may present.

The premanufacture review program, developed by EPA to implement section 5 of TSCA, is commonly referred to as the New Chemical Program. Any chemical not included in the TSCA Inventory of Chemical Substances is considered a "new" chemical. The Inventory covers chemicals in commercial production between the years of 1975 and 1979, and is regularly updated by the Agency to include newly manufactured or imported chemicals. In addition, TSCA authorizes premanufacture review of "significant new uses" of existing chemicals, as may be defined by rule at the discretion of the EPA Administrator.

In either instance, a manufacturer or importer (submitter) is required to submit to EPA advance notification of intent to manufacture or import a new chemical substance, or manufacture, import, or process an existing chemical substance for a designated significant new use. The submitter is required to complete a premanufacture notification (PMN) form which includes the substance identity, proposed uses, estimated production volume, and exposure data, including information on disposal. Although toxicological data need not be developed solely for the PMN's, it must be submitted to the extent that they are known or reasonably ascertainable by the submitter. However, as discussed below, EPA has broad authority to obtain such data when it is needed for evaluation of potential risks.

In addition, if a rule requiring testing of the chemical has been promulgated under TSCA section 4, the manufacturer must submit data developed from that testing. With respect to chemicals subject to such testing rules, the Administrator must either initiate regulatory action under TSCA sections 5, 6, or 7, or publish in the FEDERAL REGISTER a statement of reasons why such regulatory action is not being initiated. The same requirement applies to chemicals previously listed by the Administrator under TSCA section 5(b)(4) as potentially presenting an unreasonable risk, and to any proposed chemical use that has been designated by rule under TSCA section 5(a)(2) as a significant new use.

EPA has 90 days to review the information in the PMN, determine whether regulatory action is required, and take one of the actions discussed in the following overview. For good cause

EPA may extend the review period for an additional 90 days. This is most often done to allow EPA to take regulatory action. Companies are encouraged to agree to voluntarily suspend the review time if they are preparing additional information.

Each notice proceeds through a screening process to determine whether more detailed review is required and to identify candidates for regulatory action. Thus, EPA focuses on the relatively few new chemicals of greatest concern - those which are structurally related to known toxic chemicals, and those about which little is known. EPA undertakes an in-depth review of these chemicals in order to determine whether the chemicals may present unreasonable risks. The review includes analyses of available test data on the chemical and/or structurally analogous chemicals, potential human and environmental exposures, additional uses which could significantly alter exposure, the benefits of the chemical, and the relative risks posed by substitutes.

Since the inception of the New Chemical Program in July 1979, EPA has received and reviewed increasing numbers of PMN's each fiscal year (FY) [NOTE: A fiscal year begins on October 1st of the preceding calendar year.] In FY 1983, for example, 1,301 PMN's were received, as compared with 281 in FY 1980. Most PMN's reviewed do not warrant regulatory action. In a number of cases, however, the Agency has acted to obtain additional data from submitters or to control exposures to substances which are suspected of presenting unreasonable risks. These actions include formal regulatory actions, such as TSCA section 5(e) orders, and informal measures, such as negotiations with PMN submitters to obtain voluntary testing or controls.

This report, the second of an ongoing series of annual New Chemical Program activity reports, represents a complete compilation of major actions taken by the Agency in response to PMN submissions. It provides an overview of completed actions, both formal and informal, from July 1, 1984 through June 30, 1985. Volume I provides information on actions from the inception of the New Chemical Program through June 30, 1984.

Please direct questions or comments on this report to Margaret Stasikowski, Director, Chemical Control Division (TS-794), Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460.

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## OVERVIEW OF PMN PROGRAM ACTIONS

In the event that potential health or environmental concerns are identified during premanufacture review, EPA may find that additional data are necessary to determine whether proposed uses of a chemical will present an unreasonable health or environmental risk. In such cases, the Agency may prohibit or limit manufacture of the chemical under TSCA §5(e) pending development of the necessary data. Alternatively, the Agency may pursue informal courses of action through negotiations with PMN submitters to obtain additional test data or other information. Section 5(e) orders may also be issued when the data are insufficient to permit a reasoned evaluation of the potential effects of the substance, and the substance will be produced in substantial volume and result in significant exposure.

When unreasonable health or ecological effects are indicated by existing data, the Agency may prohibit or limit the manufacture, processing, or use of the substance under the provisions of TSCA §5(f). Under this section, EPA may issue an administrative order or an immediately effective rule.

Sections A and B below describe briefly the various formal and informal mechanisms by which EPA may address concerns raised during premanufacture review. Formal actions under TSCA are discussed in order of decreasing regulatory stringency, beginning with section 5(f) orders. Section C discusses a third possible outcome of the concerns raised during premanufacture review: withdrawal by the submitter of the PMN from the review process.

### A. Formal Section 5 Regulatory Actions

1. Section 5(f) Orders or Rules. Under TSCA section 5(f), the Agency may issue a proposed order which prohibits the activities described in the PMN if it finds that there is a reasonable basis to conclude that the PMN substance will present an unreasonable risk of injury to human health or the environment. Alternatively, EPA may, upon the same finding, issue a proposed rule limiting the activities described in the PMN. Such a proposed rule is effective immediately upon its publication in the FEDERAL REGISTER. To date, the Agency has issued three rules, and no orders, under section 5(f).
2. Unilateral Section 5(e) Orders. EPA may issue a proposed section 5(e) Unilateral Order if the Agency determines that 1) the information available is insufficient to permit a reasoned evaluation of the health and environmental effects of the PMN substance, and 2) in the absence of such information, the activities described in the PMN may present an unreasonable risk of injury to health or the environment, or 3) the substance will be produced in substantial quantities, and either enters or may enter the environment in substantial quantities or

may result in significant or substantial human exposure. All of the unilateral orders issued to date have prohibited the manufacture, processing, distribution in commerce, use, or disposal of the substance pending the submission and evaluation of test data addressing the health or environmental concern.

3. Section 5(e) Consent Orders. A section 5(e) Consent Order, mutually agreed to by the PMN submitter and EPA, requires the same findings as those for a Unilateral Order. Most section 5(e) consent orders specify requirements to control exposures to the substances and insure that persons who may be exposed are properly notified. These requirements may include protective equipment such as impervious gloves, safety goggles, or respirators, worker training programs, warning labels, customer notification letters, and disposal limitations. In addition, some section 5(e) orders include "testing triggers". These triggers provide that upon reaching a specified production volume, the submitter must cease production of the PMN substance unless it submits the results of a specified test which permits a reasoned evaluation of the effects of exposure.

B. Informal Regulatory Actions Under Section 5 - Voluntary Testing

EPA frequently identifies a potential unreasonable risk that can be addressed through testing the substance. In such cases, the submitter may request a suspension of the notice review period and voluntarily test the PMN substance using a mutually agreed upon protocol. EPA then evaluates the test results to determine whether the data confirm or refute the Agency's concerns. The significance of the risk would determine whether additional regulatory action is necessary.

C. Withdrawal of PMN's

A PMN submitter may withdraw a PMN from review at any time. Certain PMN submitters have chosen to do this when EPA has identified potential unreasonable risks with respect to the activities described in the PMN. EPA would otherwise address such risk through either an informal or formal regulatory action. Once a PMN is withdrawn, the manufacturer or importer must submit another notice, which is subject to another 90-day review period, before manufacture or import can begin.

PART A. FORMAL REGULATORY ACTIONS

1. SECTION 5(f) RULES

MANUFACTURED DOMESTICALLY

SECTION 5(f) RULES

MANUFACTURED DOMESTICALLY

84-529

Chemical Name: Mixed Mono- and Diamides of an Organic Acid

The Agency raised concerns for this chemical upon learning that the addition of nitrites to the PMN substance during product use could result in the formation of nitrosamines, which are known carcinogens. By issuing a section 6(a) rule under TSCA, which became immediately effective under section 5(f), the Agency required customer notification and labeling to prevent the addition of nitrites and other nitrosating agents to the substance.

PART A. FORMAL REGULATORY ACTIONS

2. SECTION 5(e) CONSENT ORDERS  
MANUFACTURED DOMESTICALLY

SECTION 5(e) CONSENT ORDERS

MANUFACTURED DOMESTICALLY

83-1157,-1222,-1227,-1228,-1229

Chemical Name: 83-1157 Substituted Oxirane  
83-1222 Substituted Alkyl Halide  
83-1227 Perhalo Alkoxy Ether  
83-1228 Perhalo Alkoxy Ether  
83-1229 Perhalo Alkoxy Ether

During the review of this chemical, the Agency raised concerns for carcinogenicity and pulmonary edema. A section 5(e) Consent Order was developed pending a two-year rodent bioassay and a 90-day subchronic inhalation study. The Order requires workers to use appropriate protective equipment, including air-supplied, positive pressure respirators, impervious full-body covering, safety goggles and impervious gloves. In addition, the Company is required to inform workers of the potential risk and of the terms of the Order.

83-1162

Chemical Name: Substituted Pyridine

EPA negotiated an Order requiring use of protective equipment pending a two-year rodent bioassay. The equipment includes impervious gloves and suits, goggles and cartridge respirators approved for organic vapor. Concerns are for liver and kidney toxicity effects and carcinogenicity.

83-1163

Chemical Name: Substituted Pyridine

Liver and kidney toxicity concerns brought about negotiations for a section 5(e) Consent Order for this chemical. The Order remains in effect pending a 90-day subchronic inhalation study. Workers are also required to use protective equipment.

## SECTION 5(e) CONSENT ORDERS

### MANUFACTURED DOMESTICALLY

84-111, -112, -113, -114, -115, -116, -117

Chemical Name: Substituted Aromatic Polymer

Concern for cancer and male reproductive effects brought about this section 5(e) Consent Order. Under the terms of the Order protective equipment during manufacture, pending the receipt of data developed in a two-year rodent bioassay is required. The protective equipment includes face shields, gloves and protective clothing. Also, the Company is required to provide warning information to its employees exposed to the substance.

84-274

Chemical Name: Poly(oxy-1,4-butanediyl)-alpha-(1-oxo-2-propenyl)-omega-[(1-oxo-2-propenyl)oxy]

Because of concern for carcinogenicity, EPA developed a section 5(e) Consent Order which requires workers to wear protective equipment pending a two-year bioassay. The protective equipment includes impervious gloves, safety goggles and protective clothing during manufacturing, processing, and use operations. Distribution of the chemical is limited to customers who will both process and use the chemical, and the Company is required to notify customers of EPA findings and restrictions placed on the chemical. In addition, the Company is required to notify employees of the proper safety precautions. The containers of the PMN substance are to be clearly labeled, and specific recordkeeping requirements are to be met.

84-358

Chemical Name: Polyaromatic Urethane Poly(unsaturated)ester

EPA raised concerns for carcinogenicity during review of this chemical. Pending a two-year rodent bioassay, EPA and the submitter negotiated a section 5(e) Consent Order requiring appropriate protective equipment, notification letters, and labeling. Distribution of the PMN substance is also limited.

SECTION 5(e) CONSENT ORDERS

MANUFACTURED DOMESTICALLY

84-491, 84-492

Chemical Name: 84-491 Substituted Aliphatic Acid Halide  
84-492 Substituted Hydroxylamine

EPA raised carcinogenicity concerns for unprotected workers exposed to the PMN substances. Pending a two-year bioassay, the section 5(e) Consent Order requires the use of impervious gloves and protective clothing by workers when handling either substance, as well as the use of respirators when workers are exposed to vapors of 84-491. Wastes resulting from production of 84-491 must be incinerated. Wastes resulting from production of 84-492 must be treated so that the 84-492 content is less than 10 ppm prior to discharge.

84-527, 84-537

Chemical Name: 84-527 Unsaturated Amino Alkyl Ester Salt  
84-537 Unsaturated Amino Ester Salt

Potential carcinogenicity concerns and possible significant dermal exposure during manufacture, processing and use were a reason for a section 5(e) Consent Order on these substances. The Consent Order requires the Company to inform workers of the hazard, and provide labeling. The Order requires workers to wear protective clothing, gloves and goggles, pending a two-year rodent bioassay. In addition, controls on use, commercial distribution, and discharge of waste will be implemented.

84-558

Chemical Name: Carboxylated Alkane Diol

Dermal and inhalation exposure for workers during manufacture, processing and use were grounds for a section 5(e) Consent Order. Pending a two-year rodent bioassay, the Order requires personal protective equipment to be worn to prevent exposure to the potential carcinogen.



## SECTION 5(e) CONSENT ORDERS

### MANUFACTURED DOMESTICALLY

#### 84-814

Chemical Name: Polysubstituted Polyol

This section 5(e) Consent Order was the first requiring processors to become co-signers of the Order and subject to its terms. This measure allows EPA to exercise greater control over use of the PMN substance pending the development of a two-year bioassay. The Order was prepared as a result of Agency concerns for carcinogenicity and mutagenicity.

#### 84-839

Chemical Name: Polyfunctional Aziridine

Carcinogenicity and mutagenicity concerns brought about this section 5(e) Consent Order. Under the terms of the Order, protective equipment in the form of impervious gloves, goggles, protective clothing and respirators is required for workers, pending a two-year rodent bioassay.

#### 84-860

Chemical Name: Disubstituted Nitrobenzene

EPA raised carcinogenicity concerns during review of this PMN substance. A section 5(e) Consent Order was developed pending a two-year rodent bioassay. The Order requires workers to wear protective equipment in the form of impervious gloves, goggles and protective clothing when handling this substance.

#### 84-902

Chemical Name: Brominated Aryl Amine

Concerns for workers exposed to this chemical include carcinogenicity, chronic effects, and mutagenicity. A section 5(e) Consent Order resulting from these concerns requires protective equipment for potentially exposed workers, pending a two-year bioassay and a 90-day subchronic study. In addition, the Order restricts the physical form in which the PMN substance may be distributed.

## SECTION 5(e) CONSENT ORDERS

### MANUFACTURED DOMESTICALLY

#### 84-913

Chemical Name: N-N'-Bis(2-(2-(3-Alkyl)vinyl)-1,4-phenylene  
diamine Double Salt

Extreme acute effects and possibly death were the concerns raised during the assessment of the PMN. Pending acute toxicity testing for this PMN substance, the conditions of the section 5(e) Consent Order require the use of personal protective equipment (goggles, gloves, chemical respirators) as well as labeling, a notification letter with disposal and first aid procedures, and certain restrictions on manufacture and distribution of the chemical.

#### 84-951

Chemical Name: Substituted Aminobenzoic Acid Ester

During review of this chemical, EPA raised carcinogenicity concerns for unprotected workers. The section 5(e) Consent Order requires protective equipment such as impervious gloves, goggles, and protective clothing, pending testing in the form of a two-year rodent bioassay.

#### 84-963

Chemical Name: 6-Nitro-2(3H)-benzoxazolone

EPA developed section 5(e) Consent Order when carcinogenicity concerns arose during review. The Order requires workers to wear protective equipment in the form of impervious gloves, pending a two-year rodent bioassay.

#### 84-1007

Chemical Name: 3-Alkyl-2-(2-anilino) Vinyl Thiazolinium Salt

Extreme acute effects and possibly death were the concerns raised during the assessment of the PMN. Pending acute toxicity testing for this PMN substance, the section 5(e) Consent Order requires the use of personal protective equipment in the form of safety goggles, impervious gloves, and chemical respirators. The Order also requires labeling, a notification letter with disposal and first aid procedures, and certain restrictions on manufacture and distribution of the chemical.

## SECTION 5(e) CONSENT ORDERS

### MANUFACTURED DOMESTICALLY

84-1042

Chemical Name: Methylammonium N-methyldithiocarbamate

The Agency raised concerns for carcinogenicity, mutagenicity, teratogenicity and neurotoxicity. EPA developed a section 5(e) Consent Order requiring protective equipment pending the receipt of the following data: a two-year bioassay, a two-generation reproductive assay, a two-species teratology study, neuropathy testing with correlative functional observation and acute exposure neurotoxicity testing.

84-1062

Chemical Name: Methyl Vinyl Sulfone

Concerns for carcinogenicity and mutagenicity for workers exposed during manufacture and use of this substance were the basis for a section 5(e) Consent Order. The Order requires protective equipment for workers in the form of impervious gloves, safety goggles, and protective clothing, pending the development of a two-year rodent bioassay.

84-1068

Chemical Name: N-Dimethylthiocarbamylthio-N'-phenyl Urea

EPA developed this section 5(e) Consent Order when concerns for cancer, developmental toxicity, and neurotoxic effects surfaced in review. The Order requires workers to wear gloves, protective clothing, and chemical safety goggles, pending a two-year bioassay, a developmental toxicity study and neurotoxicity testing.

84-1074

Chemical Name: Polyurethane Polymer

The Agency decided to develop a section 5(e) Consent Order because of a concern for carcinogenicity of low molecular weight species. The Order requires dermal protection, warning labels, and a letter and Material Safety Data Sheet (MSDS) notifying users of the requirements of the Order and the hazard concerns, pending a two-year rodent bioassay. The Company plans to perform an analytical study on the PMN substance to determine if the amount of low molecular weight species can be controlled.

## SECTION 5(e) CONSENT ORDERS

### MANUFACTURED DOMESTICALLY

84-1079

Chemical Name: Alkylated Diphenyl Oxide

EPA identified possible developmental and reproductive toxicity effects for this PMN during review. The Agency developed a section 5(e) Consent Order which requires chemical safety goggles, impervious gloves and protective clothing to control worker exposure, pending a developmental toxicity screening test.

84-1167

Chemical Name: Epoxy Ester

Information obtained during review led to a concern for the carcinogenicity of this substance. The section 5(e) Consent Order requires impervious gloves, protective clothing and chemical safety goggles for workers, pending a two-year rodent bioassay.

84-1184

Chemical Name: Polychlorofluoro Aromatic Alkylated Hydrocarbon

Carcinogenicity concerns brought about the development of this section 5(e) Consent Order. The requirements of the Order include the use of impervious gloves, a Material Safety Data Sheet (MSDS) and a label that warns of potential effects pending a two-year rodent bioassay.

85-118

Chemical Name: Polyurethane

Potential carcinogenicity was the basis of this section 5(e) Consent Order. Pending a two-year bioassay, the Order limits worker exposure and requires impervious gloves, safety goggles, protective clothing and respirators.

85-301

Chemical Name: Urethane Acrylate

A section 5(e) Consent Order was negotiated to address carcinogenicity concerns that arose during review. The Order requires the use of protective equipment in the form of impervious gloves, safety goggles and protective clothing pending a two-year rodent bioassay.

PART A. FORMAL REGULATORY ACTIONS

3. SECTION 5(e) CONSENT ORDERS  
W/TESTING TRIGGER

MANUFACTURED DOMESTICALLY

SECTION 5(e) CONSENT ORDERS  
W/TESTING TRIGGER

MANUFACTURED DOMESTICALLY

83-1033

Chemical Name: C<sub>6-8</sub> Carboxylic Acid

The section 5(e) Consent Order for this PMN includes a production volume trigger, at which time the Company must submit developmental toxicity data. The Order also requires gloves, notification letters, labels, and a Material Safety Data Sheet (MSDS).

84-393

Chemical Name: 2-Chloro-N-methyl-N-substituted acetamide

Concerns arising during review of this chemical are potential kidney and liver effects in humans, and toxicity to aquatic organisms. The section 5(e) Consent Order requires use of gloves and respirators by workers. The Order also requires that aquatic toxicity testing and a 90-day oral subchronic toxicity study be conducted when specified production volumes are reached.

84-417

Chemical Name: Substituted Phenol

EPA developed this section 5(e) Consent Order to address concerns for liver, kidney and respiratory effects. The Order requires workers to wear impervious gloves. Also, once the production volume reaches a certain volume, production must cease until the Company submits the results of a 28-day subchronic dermal study.

84-464

Chemical Name: Halogenated Aromatic Ether

This section 5(e) Consent Order requires gloves, protective clothing, chemical safety goggles, and respirators as a result of Agency concerns for liver, kidney and thyroid effects. Once the production volume reaches a certain volume, production must cease until the Company submits results of a 90-day subchronic oral toxicity test.

SECTION 5(e) CONSENT ORDERS  
W/TESTING TRIGGER

MANUFACTURED DOMESTICALLY

84-482

Chemical Name: Urea, condensate with Poly[oxy(methyl-1,2-ethanediyl)]-alpha-2-(2-aminomethylethyl)-omega-(2-aminomethylethoxy)

EPA found that insufficient information was available to evaluate this substance, and that it would be produced in substantial volume and that exposure could be significant. Under the terms of the Order, 28-day subchronic testing is required when a specified production volume is reached.

84-660, 84-704

Chemical Name: 84-660      Substituted Aryl Olefin  
84-704      Substituted Alkyl Arene

Chronic liver and kidney effects, neurotoxic, reproductive and teratogenic effects are the concerns leading to this section 5(e) Consent Order. The Order restricts the PMN substance to a maximum production volume pending 90-day subchronic testing to address the health effects. The Order requires workers to wear chemical safety goggles, impervious gloves, respirators and protective clothing while handling this PMN substance.

84-824

Chemical Name: Brominated Aromatic

Concerns for workers exposed to this chemical include carcinogenicity, pulmonary effects, chronic effects and mutagenicity. A section 5(e) Consent Order requires protective equipment for potentially exposed workers. The Order also includes a testing trigger requiring a 90-day subchronic study, and restricts the physical form in which the PMN substance will be distributed.

84-901

Chemical Name: Brominated Aryl Carbonate

Concerns for workers exposed to this chemical include chronic effects and developmental effects. A section 5(e) Consent Order resulting from these concerns requires protective equipment for potentially exposed workers. The Order includes a testing trigger requiring a 90-day subchronic study and a second generation reproductive study.

SECTION 5(e) CONSENT ORDERS  
W/TESTING TRIGGER

MANUFACTURED DOMESTICALLY

84-903

Chemical Name: Brominated Aryl Amine

Concerns for workers exposed to this chemical include carcinogenicity, chronic effects and mutagenicity. A section 5(e) Consent Order resulting from these concerns requires protective equipment for potentially exposed workers. The Order includes a testing trigger requiring a 90-day subchronic study. In addition, the physical form in which the PMN substance will be distributed is restricted.

84-968

Chemical Name: Alkyl Ester

The Agency raised concerns for developmental effects during the initial review of the chemical. When the Company declined to perform testing, and further concerns for worker and consumer exposure were raised, a unilateral section 5(e) Order was issued. When the Company submitted new exposure data which explained the limitation of the chemical's use, the consumer exposure concerns were eliminated. The concerns for unprotected workers exposed dermally and via inhalation were the grounds for a section 5(e) Consent Order. This Order included a testing trigger for developmental toxicity testing.

84-1145

Chemical Name: Alkyltrialkoxysilane

EPA negotiated a section 5(e) Consent Order to address the Agency's concern for chronic toxicity of this PMN substance. The Order requires chemical safety goggles, impervious gloves, respirators, protective clothing and includes a testing trigger for a 28-day repeated dose inhalation study.



PART A. FORMAL REGULATORY ACTIONS

4. SECTION 5(e) CONSENT ORDERS  
IMPORTED

## SECTION 5(e) CONSENT ORDERS

### IMPORTED

#### 84-7

Chemical Name: N,N,N',N'-Tetraglycidyl-1,3-bisaminomethyl  
cyclohexane

Concerns for carcinogenicity and reproductive effects arose during review of this chemical. The section 5(e) Consent Order requires use of respirators during spraying operations, gloves, and face shields, pending a 90-day subchronic inhalation study, a two-year dermal carcinogenicity study, and a two-generation reproductive study.

#### 84-341,-342,-343,-344

Chemical Name: 84-341 Poly[oxy(1-oxo-1,6-hexanediyl)]-alpha-hydro-omega-hydroxy-, ester with 3-hydroxy-2,2-dimethylpropyl-3-hydroxy-2,2-dimethyl propanoate(2:1), di-2-propanoate

84-342 Poly[oxy(1-oxo-1,6-hexanediyl)]-alpha-(1-oxo-2-propenyl)-omega-[(tetrahydro-2-furanyl)methoxy]-

84-343 Poly[oxy(1-oxo-1,6-hexanediyl)]-alpha-hydro-omega-hydroxy-, ester with 2,2'-[oxybis(methylene)]bis[2-(hydroxymethyl)-1,3-propanediol]2-propanoate, 2-propanoate

84-344 2-Propenoic acid, [2-[1,1-dimethyl-2-[(1-oxo-2-propenyl)oxy]ethyl]-5-ethyl-1,3-dioxan-5-yl] methyl ester

Carcinogenicity concerns raised by the Agency during review brought about negotiations for a section 5(e) Consent Order. Pending a two-year rodent bioassay, the Order requires the use of protective equipment in the form of impervious gloves, safety goggles and protective clothing. In addition, the importer will only sell to those customers who will both process and use these substances.

PART B. INFORMAL REGULATORY ACTIONS

1. VOLUNTARY TESTING

MANUFACTURED DOMESTICALLY

## VOLUNTARY TESTING

### MANUFACTURED DOMESTICALLY

84-18

Chemical Name: 1-(1,1-Dimethylethoxy)-propan-2-ol

The Agency raised concerns for potential worker and consumer exposure to the PMN substance which was believed to cause blindness and adverse blood effects. The Company provided eye irritation tests which proved to be negative. The Company is currently performing 90-day subchronic testing by the inhalation route. The review period is suspended pending the receipt of the additional data.

84-498

Chemical Name: Fatty Alcohol, Ethoxylated, Propoxylated, Fatty Acid Ester

Aquatic toxicity concerns prompted the Agency to request further information on this PMN substance by means of a negotiated section 5(e) Order. The Company, however, decided to complete acute aquatic toxicity testing prior to manufacturing the substance. Review of the data mitigated the Agency's concern, and the Company was allowed to manufacture the substance.

84-780

Chemical Name: Aliphatic Diacrylate

At the Agency's request, a mouse lymphoma assay was performed by the Company which submitted this substance for review. The negative results of this test alleviated the Agency's concerns for the carcinogenicity of this chemical.

84-792

Chemical Name: Disubstituted Anthraquinone-2-sulfonic Acid, Alkali Metal Salt

The PMN substance was reviewed for acute aquatic toxicity concerns. EPA required a series of acute aquatic toxicity data before the Company was allowed to manufacture the chemical. The Company, subsequently, submitted data to address these concerns under a voluntary suspension. The review of the data indicates that the chemical will not pose an unreasonable risk.

## VOLUNTARY TESTING

### MANUFACTURED DOMESTICALLY

#### 85-30

Chemical Name: Carbopolycycle Sulfonate of Substituted  
Phenyl Azo Substituted Heteromonocycle

The Company voluntarily performed eye irritation testing to address acute lethality concerns. The results of the testing were negative. Further testing to address aquatic toxicity concerns was conducted. The PMN was dropped from review following the evaluation of test results.

#### 85-321

Chemical Name: Substituted Phenol/Formaldehyde Resin

EPA raised concerns for the potential aquatic toxicity effects of the PMN substance. The submitter conducted acute testing on algae and Daphnia. The test results mitigated EPA's concerns for the PMN substance and no formal regulatory action was taken.

#### 85-410

Chemical Name: Amine Substituted Imidazolidines

The submitter provided the Agency with aquatic toxicity testing data to aid in the review of the case. Although test results indicate a high degree of toxicity to fish and aquatic invertebrates, the expected concentration levels of the PMN substance entering the receiving streams mitigated the Agency's concerns, and the case was dropped from review.

PART B. INFORMAL REGULATORY ACTIONS

2. VOLUNTARY TESTING

IMPORTED

## VOLUNTARY TESTING

### IMPORTED

#### 83-860

Chemical Name: Metal Complexed Substituted Aromatic Azo Compound

The Agency raised concern for carcinogenicity of metabolites of the PMN substance. The Company conducted analytical testing and metabolism testing of the PMN substance. The results confirm the formation of the metabolites. The PMN is currently suspended pending negotiation of additional testing.

#### 83-1006

Chemical Name: (Amino)-(hydroxy)-(substituted)-(substituted)-naphthanedisulfonic acid, and (amino)-(hydroxy)-(substituted)-(substituted)-naphthanedisulfonic acid, salts with sodium and potassium

Concern over carcinogenicity of potential metabolites brought about the Agency's request for mutagenicity testing on this chemical. The Company performed a modified Ames test and results were received. The results mitigated the Agency's concerns and the case was dropped with no further action.

#### 83-1007

Chemical Name: (Substituted)-(substituted)-hydroxy-naphthalene-sulfonic acid, sodium salts

A modified Ames test was performed on this substance to address mutagenicity concerns for potential metabolites. The results of the voluntary action were sufficient to eliminate the Agency's concern for mutagenicity.

#### 83-1012

Chemical Name: Bis[sulfophenylchlorotriazineaminosulfophenylazo]-hydroxyaminodisulfonaphthalene

The Company performed a modified Ames test to address the concerns for mutagenicity. The results were inconclusive. Following the review of additional data, the Agency's concerns were mitigated and the case was dropped from review.

## VOLUNTARY TESTING

### IMPORTED

83-1018

Chemical Name: Substituted-naphthalene tetrazodisulfonic acid,  
bis[(substituted-hydroxyphenylazo)phenyl]derivative

A modified Ames test, conducted by the submitter to address carcinogenicity concerns, was positive for the substance. The case is currently suspended pending negotiation of further testing or other regulatory options with the Company.

84-64

Chemical Name: Substituted-phenylamino monochloro-triazinylamino-sulfophenyl azo-substituted disulfononaphthalenylazo-naphthalenedisulfonic acid, hexasodium salt

Mutagenicity (modified Ames) testing was performed on this PMN substance to address carcinogenicity concerns. Results were received and reviewed, but required further clarification to be conclusive. Based on additional data, the Agency subsequently dropped concern for the PMN substance.

84-68

Chemical Name: Substituted Anthraquinone Aryl Amine

This PMN compound is believed to present an unreasonable risk to aquatic organisms based on data included in the PMN and supporting data on structural analogues. The Agency requested that the submitter address these concerns by conducting acute toxicity tests on algae, Daphnia and fish. The Company completed the aquatic fish testing, submitted the data to EPA, but decided against further testing and withdrew the PMN.

84-490

Chemical Name: Substituted Aminofluorane

This submitter performed mutagenicity testing to address the Agency's concern for carcinogenicity. The PMN was dropped from further review based on the results of the testing and review of additional information.



VOLUNTARY TESTING

IMPORTED

84-927

Chemical Name: Carbopolycyclic Alkenyl Ether

A sister chromatid exchange test for mutagenic effects was performed voluntarily on this chemical, with negative results. The Agency requested testing to address oncogenicity concerns. Following evaluation of the test results, the PMN was dropped from review.

PART C. PMN's WITHDRAWN

1. PRIOR TO LIKELY SECTION 5(e) ACTION  
MANUFACTURED DOMESTICALLY

PMN's WITHDRAWN IN FACE OF LIKELY §5(e) ACTION

MANUFACTURED DOMESTICALLY

83-1029

Chemical Name: Substituted Heterocycle

Mutagenicity, carcinogenicity, liver and central nervous system effects are the concerns that prompted negotiation of a section 5(e) Consent Order. The Company later decided to withdraw the PMN rather than enter into the terms of the Order.

84-306, 84-307

Chemical Name: 84-306 Benzoic acid, 2-[[[2-[(2-methyl-1-oxo-2-propenyl)oxy]ethyl]amino]carbonyl]oxy-methyl ester  
84-307 2-Propenoic acid, 2-methyl-, 2-[[hexahydro-2-oxo-1H-azepin-1-yl]carbonyl]amino]ethyl ester

The Agency raised concerns for carcinogenicity and potential significant exposure to workers. A section 5(e) Consent Order was negotiated to limit the use of the PMN substances. The submitter withdrew the PMN's rather than sign the section 5(e) Consent Order.

84-462

Chemical Name: Substituted Urethane Ester

The Agency required the submitter to conduct mutagenicity testing. The submitter decided to withdraw the chemical rather than perform the testing.

84-840

Chemical Name: Modified Epoxy Resin

EPA proposed a section 5(e) Consent Order to provide controls for the workers. The submitter was not willing to require protective equipment because of the operation methods used in manufacturing this type of product, and withdrew in the face of the proposed action.

PMN's WITHDRAWN IN FACE OF LIKELY §5(e) ACTION

MANUFACTURED DOMESTICALLY

84-858

Chemical Name: Polyalkylene Glycol Ether Acrylate

Concerns for carcinogenicity were raised for possible significant exposure to workers. A section 5(e) Consent Order was prepared to address these concerns, and to limit the use of the substance. The Company chose to withdraw their substance in the face of these developments.

84-953

Chemical Name: Reacted Epoxy Resin

A section 5(e) Consent Order was recommended for this PMN, based on significant exposure and sufficient data to present health concerns. Concerns involved carcinogenicity, mutagenicity and fetotoxicity. The Company instead chose to withdraw the chemical from premanufacture notice review.

84-1051

Chemical Name: Halogenated Aromatic Substituted Olefin

This Company chose to withdraw this substance from review rather than comply with the terms of a section 5(e) Consent Order. Concerns arose over liver, kidney, neurotoxic, reproductive and teratogenic effects.

84-1189

Chemical Name: Modified Acrylamide Polymer

Ecotoxicity concerns prompted a section 5(e) Consent Order for this substance. The Company, however, did not feel it was economically feasible to perform the required testing, and withdrew the chemical.

85-1190

Chemical Name: Modified Acrylamide Polymer

Ecotoxicity concerns prompted a section 5(e) Consent Order for this substance. The Company, however, chose to withdraw the chemical rather than perform the required testing.

PMN's WITHDRAWN IN FACE OF LIKELY §5(e) ACTION

MANUFACTURED DOMESTICALLY

84-1227

Chemical Name: Halogenated Aromatic Substituted Alkane

During review of this chemical, EPA developed concerns for neurotoxic, liver, kidney, reproductive, and teratogenic effects. The Company withdrew the chemical from review rather than comply with a section 5(e) Consent Order.

85-2

Chemical Name: Nitro Alcohol

Review of the chemical indicated concerns for oncogenicity, mutagenicity, neurotoxicity and general toxicity. Exposure to workers was significant, bringing about the Agency's decision to develop a section 5(e) Consent Order. The Company chose to withdraw the chemical from review.

85-152

Chemical Name: Reacted Epoxy Resin

The concerns identified by the Agency were for possible ecotoxicity and severe liver toxicity. EPA decided to require ecotoxicity data prior to manufacture. The results from the ecotox testing mitigated the ecotox concern. A section 5(e) Consent Order involving a testing trigger to require a 90-day subchronic toxicity test was under preparation. The Order also required protective equipment. The submitter decided to withdraw the case instead of performing the testing for health concerns.

85-153

Chemical Name: Reacted Epoxy Resin

EPA recommended a section 5(e) Consent Order requiring workers to wear protective equipment, based on the Agency's concerns for oncogenicity. The Company, however, chose to withdraw.

PMN's WITHDRAWN IN FACE OF LIKELY §5(e) ACTION

MANUFACTURED DOMESTICALLY

85-297

Chemical Name: Isophorone Diisocyanate Adduct of a Polyether Glycol, an Alkanediol, and a Substituted Alkanol

Carcinogenicity concerns brought about a section 5(e) Consent Order for this chemical. The Company chose to withdraw rather than comply with the Order requirements.

85-313

Chemical Name: Substituted Alkanol Adduct of a Long Chain Diisocyanate

This Company chose to withdraw their chemical from review rather than comply with requirements of a section 5(e) Consent Order. Carcinogenicity concerns were the basis for the Agency's decision.

85-352

Chemical Name: MDI Adduct with a Polyether Glycol and a Hydroxy Methacrylate

The submitter withdrew the PMN in face of the Agency's decision to develop a section 5(e) Consent Order, requiring protective equipment. Carcinogenicity concerns, which developed while the case was under review, were the basis for the Agency's decision to develop the Order.

PART C. PMN'S WITHDRAWN

2. PRIOR TO LIKELY SECTION 5(e) ACTION  
IMPORTED

PMN'S WITHDRAWN IN FACT OF LIKELY §5(e) ACTION

IMPORTED

83-755

Chemical Name: 4-Hydroxy-6-phenylaminonaphthalene-2-sulfonic Acid

EPA raised concerns for carcinogenicity of the PMN substance and an impurity. The submitter tested the impurity in a mutagenicity screen. Results were positive. Rather than enter into a consent agreement pending a two-year bioassay, the Company withdrew the substance from PMN review.

84-277

Chemical Name: Spiroglycol

EPA would have required a section 5(e) Consent Order with protective equipment controls pending testing if the submitter decided to commence import or manufacture. The submitter decided the product would not support the testing costs and controls.

84-467

Chemical Name: Hydrogen-2-[alpha-(2-hydroxy-3-sulfo-5-ethenylsulfonylphenylazo)-benzilidenehydrazino]-5-substituted, cuprate, sodium salt

EPA requested voluntary testing to address ecotox concerns. The Company declined, and when the Agency decided a section 5(e) Consent Order would be necessary to produce testing, the Company withdrew the PMN from the review process.

84-543

Chemical Name: Glycine, N-[4-[2[4-[1-amino-8-hydroxy-7-phenylazo-3,6-disulfonaphth-2-yl]azo]phenyl]-1,3-benzodiazole-6-yl]azo-3-hydroxyphenyl]-, a trisodium salt

Carcinogenicity and worker exposure concerns brought about the Agency's requirement for Ames testing under a section 5(e) Consent Order. The Company withdrew their PMN from the review process rather than perform testing.



PMN'S WITHDRAWN IN FACT OF LIKELY §5(e) ACTION

IMPORTED

84-608

Chemical Name: Substituted Oxazinium Salt

Oncogenicity concerns developed for this chemical during review. The Agency requested a two-year bioassay from the Company, but they chose to withdraw their PMN.

85-98

Chemical Name: 2,2'-(1,3-Phenylene)bis(4,5-dihydro-oxazole)

Neurotoxicity and carcinogenicity concerns for workers developed during review of this chemical. EPA proposed a section 5(e) Consent Order requiring testing, but the Company chose to withdraw, for economic reasons, rather than test at this time.

85-232

Chemical Name: Chromate(2-), [2-[[1-(3-chlorophenyl)-4,5-dihydro-3-methyl-5-oxo-1H-pyrazol-4-yl]azo]-5-sulfobenzoato-(2)][2-[4,5-dihydro-5-oxo-1,3-diphenyl-1H-pyrazol-4-yl]azo]benzoato(2-)]-, sodium hydrogen (9CI)

This Company chose to withdraw the PMN rather than conduct a two-year bioassay to address carcinogenicity concerns, because it was not economically feasible.

85-325

Chemical Name: Cobaltate[1-], [N-[8[[5-[aminosulfonyl]-2-hydroxyphenyl]azo]-7-hydroxy-1-naphthalenyl]acetamidato[2-]]-[3-[4,5-dihydro-4-[(2-hydroxy 5-nitrophenyl)azo]-3-methyl-5-oxo-1H-pyrazol-1-yl]benzene-sulfonamidato(2-)]-, sodium (9CI).

Due to carcinogenicity concerns and uncontrolled worker exposure, a section 5(e) Consent Order pending a two-year bioassay was proposed for the PMN substance. Given this likely regulatory action, the submitter withdrew the PMN from review.

PMN'S WITHDRAWN IN FACT OF LIKELY §5(e) ACTION

IMPORTED

85-326

Chemical Name: Chromate(1-), [3-[4,5-dihydro-4-[(2-hydroxy-5-nitrophenyl)azo]-3-methyl-5-oxo-1H-pyrazol-1-yl)benzene-sulfonamidato(2-)] [4-hydroxy-3-[(2-hydroxyl-1-naphthalenyl)azo]benzenesulfonamidato(2-)]-hydrogen (9CI).

Due to carcinogenicity concerns and uncontrolled worker exposure, a section 5(e) Consent Order pending a two-year bioassay was proposed for the PMN substance. The submitter withdrew the PMN from review, in the face of this likely regulatory action.

PART C. PMN'S WITHDRAWN

3. PRIOR TO LIKELY SECTION 5(f) ACTION  
MANUFACTURED DOMESTICALLY

PMN's WITHDRAWN PRIOR TO LIKELY SECTION 5(f) ACTION

MANUFACTURED DOMESTICALLY

84-841

Chemical Name: Modified Epoxy Resin

EPA proposed to ban this PMN under section 5(f) on the basis of oncogenicity, mutagenicity, and fetotoxicity concerns and significant exposure. The submitter opted to withdraw the PMN rather than accept the terms of the section 5(f) action.

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PART C. PMN'S WITHDRAWN

4. PRIOR TO LIKELY SECTION 5(f) ACTION  
IMPORTED

PMN'S WITHDRAWN PRIOR TO LIKELY SECTION 5(f) ACTION

IMPORTED

84-576

Chemical Name: 4,4',6-Trimethyl-2-(1-propenyl)-1,3-dioxane  
(cis- and trans-)

The submitter withdrew in face of a section 5(f) Order to ban the PMN until testing was submitted. There were oncogenicity concerns and widespread exposure concerns for this chemical.

Table 1. Annual Compilation of PMN Program Actions  
Through June 30, 1985

	FY'79	FY'80	FY'81	FY'82	FY'83	FY'84	FY'85	Total
Valid PMN's Received	8	281	580	839	1301	1,192	1,106	5,307
5(e) Orders Issued	0	2 (7 PMN's)	0	1 (2 PMN's)	2 (4 PMN's)	1 (1 PMN)	1 (1 PMN)	7 (15 PMN's)
Consent 5(e) Orders Issued	0	0	0	1 (2 PMN's)	8 (12 PMN's)	19 (40 PMN's)	26 (36 PMN's)	54 (90 PMN's)
5(f) Rules Issued	0	0	0	0	0	3 (4 PMN's)	0	3 (4 PMN's)
Informal Action - Voluntary Testing	0	1	10	5	42	20	12	90
PMN's Withdrawn In Face of Likely 5(e) Order	0	1	1	1	18	34	22	77
PMN's Withdrawn In Face Of Likely 5(f) Order	0	0	0	1	2	1	1	5
Total	0	9	11	11	78	100	72	281

\*As of June 30, 1985

Table 2: Percentage of Commencement of Manufacture Notices\* Received\*\*

Valid PMN's Received		% of Notice of Commencements Received	
		<u>Number</u>	<u>%</u>
FY 79	8	6	75.0%
FY 80	281	165	58.7%
FY 81	580	367	63.3%
FY 82	839	497	59.3%
FY 83	1301	618	47.5%
FY 84	1192	490	41.1%
FY 85	1106	159	14.4%

\* After PMN review, a person who begins to manufacture or import a chemical must submit a "notice of commencement" to EPA. These chemicals are added to the TSCA Chemical Substances Inventory.

\*\* As of June 30, 1985



Table 3. Annual Compilation of PMN Activities by Specific Concern  
FY 1984

TOXICITY CONCERN

	<u>Voluntary Testing</u>		<u>§5(e) Order</u>		<u>Withdrawn in the face of a §5(e) Order</u>	
	Domestic	Import	Domestic	Import	Domestic	Import
Carcinogenicity/ Mutagenicity	2	7	32	3	6	13
Teratogenicity/ Fetotoxicity/ Reproductive Effects	2	0	14	1	3	1
Liver/Kidney	0	0	8	0	1	0
Neurotoxicity	3	0	0	0	1	1
Acute Effects	1	0	9	0	0	0
Other Chronic Toxicity	0	0	3	0	0	0
Ecotoxicity	3	2	1	0	0	6

CONCERN FOR EXPOSED POPULATIONS

	<u>Voluntary Testing</u>		<u>§5(e) Order</u>		<u>Withdrawn in the face of a §5(e) Order</u>	
	Domestic	Import	Domestic	Import	Domestic	Import
Workers	3	4	40	3	4	9
Consumers	2	0	1	0	0	1
Environment	0	3	0	0	0	5
General Population	0	1	0	0	0	1

Table 3. Annual Compilation of PMN Activities by Specific Concern  
FY 1985\*

TOXICITY CONCERN

	<u>Voluntary Testing</u>		<u>§5(e) Order</u>		<u>Withdrawn in the face of a §5(e) Order</u>	
	Domestic	Import	Domestic	Import	Domestic	Import
Carcinogenicity/ Mutagenicity	1	6	23	4	8	5
Teratogenicity/ Fetotoxicity/ Reproductive Effects	0	0	7	0	2	0
Liver/Kidney	0	0	9	0	3	0
Neurotoxicity	0	0	4	0	3	1
Acute Effects	3	0	6	0	0	0
Other Chronic Toxicity	1	0	5	0	1	0
Ecotoxicity	4	0	1	0	4	0

CONCERN FOR EXPOSED POPULATIONS

	<u>Voluntary Testing</u>		<u>§5(e) Order</u>		<u>Withdrawn in the face of a §5(e) Order</u>	
	Domestic	Import	Domestic	Import	Domestic	Import
Workers	1	0	30	4	6	2
Consumers	1	0	6	0	0	0
Environment	0	0	2	0	0	0
General Population	0	0	2	0	0	0

\*As of June 30, 1985

Table 4. Historical Compilation of Specific Concerns Underlying  
Formal and Informal Regulatory Action  
Domestic U.S. Import Chemicals\*

TOXICITY CONCERN

	<u>FY' 80</u>		<u>FY' 81</u>		<u>FY' 82</u>		<u>FY' 83</u>		<u>FY' 84</u>		<u>FY'85</u>		<u>Totals</u>	
	Domestic	Import	Domestic	Import	Domestic	Import	Domestic	Import	Domestic	Import	Domestic	Import	Domestic	Import
Carcinogenicity/Mutagenicity	16	0	6	2	9	5	29	12	43	26	32	15	135	60
Teratogenicity/Fetotoxicity Reproductive Effects	3	0	0	0	2	0	3	4	19	0	9	0	36	4
Liver/Kidney	0	0	0	0	7	0	15	0	9	0	12	0	43	0
Neurotoxicity	0	0	1	0	1	0	4	0	4	1	7	1	17	2
Acute Effects	4	0	17	2	19	2	8	1	10	0	9	0	67	5
Other Chronic Toxicity	1	0	0	0	4	0	0	0	3	0	7	0	15	0
Ecotoxicity	6	0	1	1	2	0	12	1	4	8	9	0	34	10

CONCERN FOR EXPOSED POPULATIONS

	<u>FY' 80</u>		<u>FY' 81</u>		<u>FY' 82</u>		<u>FY' 83</u>		<u>FY' 84</u>		<u>FY'85</u>		<u>Totals</u>	
	Domestic	Import	Domestic	Import	Domestic	Import	Domestic	Import	Domestic	Import	Domestic	Import	Domestic	Import
Worker	14	0	16	4	15	4	39	15	47	16	37	6	168	45
Consumer	3	0	3	1	6	2	3	0	3	1	7	0	25	4
Environment	6	0	1	0	3	1	13	1	0	8	2	0	25	10
General Population	0	0	1	2	2	2	4	3	0	1	2	0	9	8

\*Through June 30, 1985

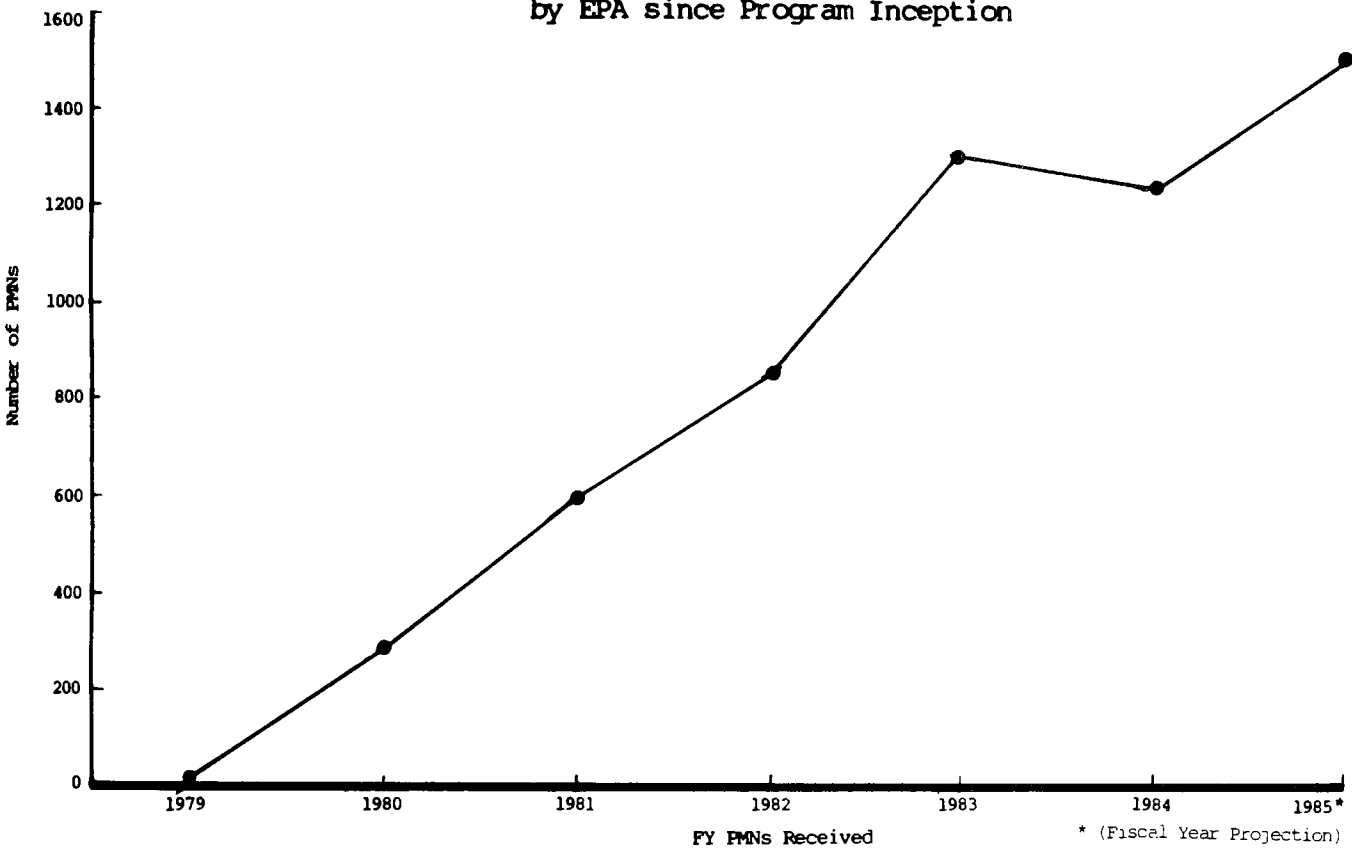
CHEMICAL CLASSIFICATION

OF ACTIONS TAKEN

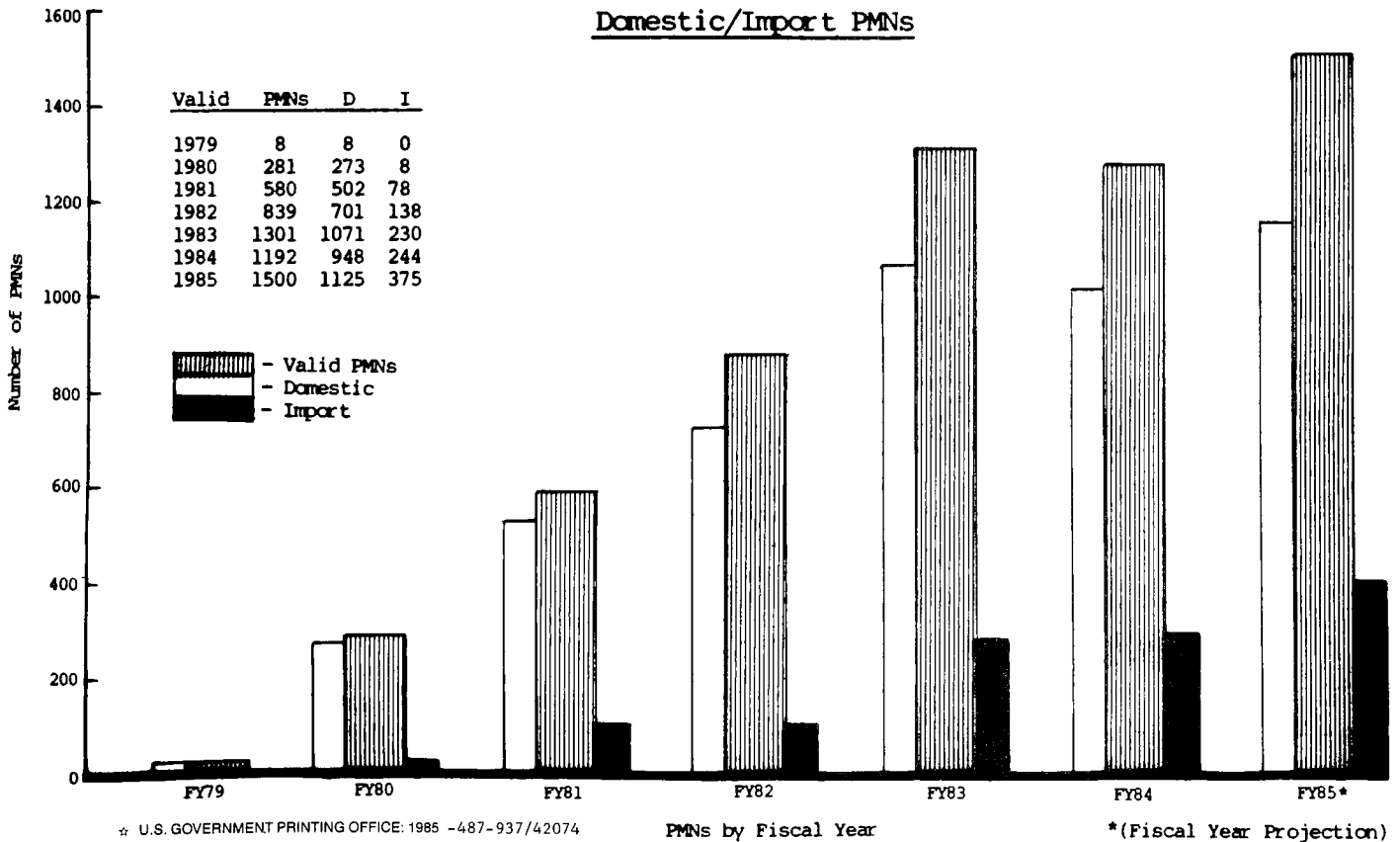
DYES & DYE INTERMEDIATES	ACRYLATES	CATIONIC POLYMERS	HETEROCYCLIC COMPOUNDS	HALOGENATED COMPOUNDS
17%	20%	3%	10%	21%

CARBOXYLIC ACIDS	GLYCOL ETHERS	EPOXIDES	OTHER
1%	1%	10%	17%

# Rate of Growth for Valid PMNs Received by EPA since Program Inception



## Domestic/Import PMNs





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