- Polmer Identity - Information on Monomers and Other Reactants, 720.45 (a) (3)

Need to identify and quantify all monomers and other reactants charged to the reactor which are intentionally used to become chemically part of the polymer. "Other agents" include crosslinking agents, chain-terminating agents, free radical initiators, etc.

Impurities such as residual solvents, surfactants or catalysts not intentionally incorporated into the polymer must be reported as impurities.

- Test Data Requirements, 720.50 (a) (3)

EPA has indicated that different amounts of detail are to be submitted depending on the type of test data that are being reported. For simple tests to determine physical properties, little more than the measurement need be provided. For toxicity tests, however, protocols, description of what was tested, information on impurities, solvents used, etc., need to be included. If workplace monitoring is conducted, this data are to be submitted.

- Use Information, 720.45(f)

EPA has maintained this requirement, but indicates that it is not necessary to obtain detailed customer use information unless it is normally done in the business. However, where we have such information, it must be submitted.

- Other Issues

EPA has maintained its position that submitters must use the form published on May 13, 1983.

Confidential Chemical Identity - EPA will determine whether the chemical identity is necessary to interpret a health or safety study. If it is, then the agency will make the identity a part of the study and available to the public whether or not it is claimed confidential.

A copy of the September 13, 1983 file rule is attached for your information.

J. E. Cearley

J. E. Cearley

JEC/tr

cc: T. L. Thoem

ABD00129269

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federal register

Tuesday
September 13, 1983

Part II

Environmental Protection Agency

Premanufacture Notification; Revision of Regulation and Partial Stay of Effective Date

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 720

[OPTS-50002J; TSH-FRL 2412-8]

Premanufacture Notification; Revision of Regulation and Partial Stay of Effective Date

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; revision of regulation and partial stay of effective date.

SUMMARY: EPA is staying the effective date of §§ 720.3(y), 720.36, 720.50(c), and 720.78(b) and issuing nonsubstantive amendments to § 720.102 of the final premanufacture notice (PMN) rule issued under section 5 of the Toxic Substances Control Act (TSCA). Under section 5 of TSCA, any person who intends to manufacture or import a new chemical substance for commercial purposes must notify EPA at least 90 days before manufacture or import begins. EPA is also clarifying other sections of the rule.

DATE: The effective date of the premanufacture notification rule, with the exception of the stayed sections, §§ 720.3(y), 720.36, 720.50(c), and 720.78(b), is October 26, 1983.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, D.C. 20460; toll-free: (800-424-9065), in Washington, D.C.: (554-1404), outside the USA: (Operator 202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

Under section 5 of TSCA, any person who intends to manufacture or import a new chemical substance for commercial purposes must notify EPA at least 90 days before manufacture or import begins. This requirement has been in effect since July 1, 1979. Since then, EPA has received and reviewed more than 2,500 notices on new substances. EPA has operated the new chemical review program under interim policies published in the Federal Register of May 15, 1979 (44 FR 28564), November 7, 1980 (45 FR 74378), and July 2, 1982 (47 FR 28969).

EPA proposed a rule to interpret section 5 requirements and to establish notification procedures in the Federal Register of January 10, 1979 (44 FR 2242). Portions of this rule were reproposed on October 16, 1979 (44 FR 59764). In addition, EPA proposed processor reporting requirements in the Federal Register of August 15, 1980 (45 FR 54642) and a clarification of importer requirements on September 23, 1980 (45 FR 63806).

After reviewing public comments and evaluating its experience in conducting the PMN program, EPA issued a final premanufacture notice rule in the Federal Register of May 13, 1983. This rule was scheduled to become effective on July 12, 1983. The rule covers the scope and applicability of section 5 requirements; the general procedures for submitting notices; information requirements, including a mandatory notice form; and EPA's procedures for processing information contained in the notices, including confidential business information.

On June 17, 1983, the Chemical Manufacturers Association (CMA) petitioned EPA to stay the effective date of the PMN rule for 90 days to provide EPA time "to clarify and modify the rule in several respects." CMA stated that, without clarification and possible modification of certain rule provisions, the rule would impose an undue burden on its member companies. CMA particularly expressed concern about: (1) The research and development (R&D) exemption, (2) the PMN notice form, (3) information requirements on polymer identity, (4) the submission of test data, (5) the submission of data on related chemicals, (6) the submission of descriptions of risk assessments, (7) the procedures for declaring PMNs "incomplete," and (8) the definition of "possession or control." In a memorandum accompanying its petition, CMA also raised questions about information requirements on use and manufacturing operations, the possible release of confidential chemical identity included in health and safety studies, the timing of substantiations of confidential chemical identity, the submission of generic use descriptions, and the timing for submitting notices of commencement of manufacture.

In addition, on June 27, 1983, the Society of the Plastics Industry (SPI) submitted a petition to EPA to stay the effective date of the PMN rule. SPI raised two issues concerning polymer information requirements—the requirements that the average molecular weight and percentage of low molecular weight species be estimated and that monomers and other reactants used at less than 2 percent by weight be identified.

In response to these petitions, EPA postponed the effective date of the rule for 60 days, so that it could review the rule language and, where necessary, clarify ambiguous points or revise specific provisions. This postponement was announced in the Federal Register of July 11, 1983 (48 FR 31641). During the postponement period, EPA has received further comments on the issues raised in the CMA and SPI petitions from SPI, CMA, the American Chemical Society, and the National Paint and Coatings Association. The CMA and SPI petitions, as well as these subsequent comments, are included in the public record on the PMN rule.

II. Summary of Action

In this notice, EPA announces that the major provisions of the TSCA section 5 PMN rule will go into effect on October 26, 1983. In addition, the notice announces the following actions with respect to the rule: (1) The stay, pending further consideration and rulemaking, of §§ 720.36 and 720.78 (requirements concerning new chemical substances manufactured under the section 5(h)(3) R&D exemption), § 720.3(y) (the definition of "possession or control"), and § 720.50(c) (data requirements on related chemicals), and (2) a nonsubstantive amendment of § 720.102(b)(1) (timing of submission of the notice of commencement of manufacture). EPA is also clarifying several other provisions of the rule (primarily those concerning polymer information requirements, test data requirements, and information requirements on risk assessments and uses), and explains why the Agency believes that other provisions identified as a concern by CMA—such as the mandatory form and incompleteness provisions—do not require revision.

Except for the sections that have been stayed, the final rule will go into effect on October 26, 1983. All PMNs received on or after that date must be submitted on the PMN form, and notice submitters must comply with the provisions of this rule that are in effect. These provisions include all the major notification and procedural requirements of the PMN rule, such as the mandatory form, test data and information requirements, procedures by which EPA can declare a notice incomplete, and confidentiality procedures.

With this notice, therefore, the basic provisions of the PMN rule will go into effect. These requirements will promote standardized PMN reporting and recordkeeping procedures; they will allow EPA more effectively to address the increasing number of PMNs it is now receiving; and they will ensure consistent enforcement of section 5 provisions. The temporary postponement of provisions concerning R&D, "possession or control," and data on related chemicals will to a certain extent increase EPA's review burden but will not place the public at greater risk from new substances during the period before final provisions are developed, and it will not adversely affect the operation of EPA's new chemical review program, which is conducted under the statutory authority of TSCA section 5.

III. Clarification of Selected Rule Provisions

CMA and SPI expressed concern about several information requirements in the final rule, in particular, requirements concerning polymer identity, test data, use information, and risk assessments. EPA believes that these concerns result in part from a misunderstanding of EPA's intentions and in part from an extreme interpretation of the rule language. By clarifying these provisions, EPA hopes to reduce industry's concerns, while ensuring that adequate data for EPA's initial review are submitted in PMNs.

1. *Polymer identity*—(a) *Molecular weight estimates.* Section 720.45(a)(3) of the rule and Part I(B)(2)(b) of the PMN form require notice submitters to estimate or provide measurements of: (i) The lowest number-average molecular weight composition of new polymers, and (ii) the maximum weight percent of low molecular weight species below 500 and 1,000 absolute molecular weight. If the PMN applies to a range of products of varying molecular weight characteristics, the manufacturer should provide data or estimates for the lowest molecular weight material, or provide information on the range of values expected.

Information on molecular weight must be provided to the extent that it is known to or reasonably ascertainable by the submitter. EPA is requiring this information concerning the specific chemical identity of the polymer because data on average molecular weight and low molecular weight species are fundamental pieces of information used in characterizing polymers and are central to polymer risk assessment. Many of the potential risks from polymers result from the lower molecular weight portions of the monomer.

EPA has been asked to clarify the extent to which the "known to or reasonably ascertainable" standard requires manufacturers to determine the exact molecular weight of new polymers, and whether a failure to do so would lead EPA to declare a PMN submission incomplete. Under this rule, submitters are not required to determine molecular weight or molecular weight distribution by analytical measurement solely for the purpose of complying with PMN requirements. Rather, they are required to provide data from actual measurements only if they have conducted those measurements, or if during the normal course of business "a reasonable person similarly situated" would have conducted these measurements.

If molecular weight or molecular weight distribution have been measured at the time of PMN submission, the resulting data must be submitted and the method of measurement identified. Some examples of analytical methods which can be used to measure molecular weight or molecular weight distribution, or which can be used to estimate these values, are: size exclusion chromatography (e.g., gel permeation), vapor pressure osmometry, light scattering, dialysis, sedimentation rate, end-group analysis, solvent precipitation, and viscosity measurements.

EPA recognizes that in many cases it is not practicable to measure polymer molecular weight directly at the PMN stage. If a manufacturer has not conducted an analysis of average molecular weight or molecular weight distribution based on measurement of the polymer itself, the PMN submitter should estimate these parameters. The estimates can be expressed as precise values or as ranges; in some cases—for example, very high molecular weight polymers—it may be possible to estimate average molecular weight only as greater than a certain level. EPA's experience with PMNs submitted without molecular weight information has been that, in most cases, the submitter has been able to estimate these values readily when contacted by the Agency. Submitters can frequently estimate molecular values on the basis of past experience (e.g., correlating observed or measured physical properties with previously measured, calculated, or estimated molecular weight values); stoichiometric relationships, including molecular weights of starting materials and expected reactions; and knowledge of process or purification steps, such as extraction, solvent precipitation, and vaporization of volatile components.

From its PMN experience, EPA believes that submitters' expert knowledge concerning the polymers they produce will generally enable them to provide a reasonable estimate of molecular weight values, and therefore, that estimated values are for the most part reasonably ascertainable. However, if a submitter is unable to provide meaningful estimates for these parameters, he or she may indicate "NK" (not known or reasonably ascertainable) on the PMN form. In such cases, the submitter should be prepared to provide an explanation of why meaningful estimates cannot be made. If a reasonable explanation cannot be provided upon request, the Agency may declare the notice incomplete.

CMA and SPI argue that the requirement to estimate the percentage of low molecular weight species involves a substantial change from the proposed requirements and that it was adopted without any notice or opportunity for comment. EPA, however, believes that this requirement does not represent a substantial departure from earlier proposed requirements for molecular weight information. Furthermore, it is consistent with EPA practice under the interim policy. When the Agency receives PMNs on polymers without this information, it has routinely contacted the PMN submitters for measured values or estimates of molecular weight. EPA has found that submitters can provide this information with minimal burden. Finally, because the requirement to submit data on polymer identity is an interpretation of the statutory requirement to identify the new substance and its molecular structure, it would not require notice and comment.

(b) *Information on monomers and other reactants.* Section 720.45(a)(3) of the rule and Part I(B)(2)(b) of the PMN form require manufacturers to identify new polymers by monomers and other reactants. This requirement remains essentially unchanged from the January 10 and October 16, 1979, proposed forms.

CMA's and SPI's petitions and previous EPA experience with polymer reporting indicate that many submitters do not understand the PMN reporting requirements as they apply to monomers and other reactants used at or below 2 percent by weight (the phrase "monomers and other reactants" is defined below). For the initial Inventory, EPA required reporting only of monomers and oher reactants used at greater than 2 percent by weight, but submitters could report those monomers and other reactants used at 2 percent and below if they wanted them included in the Inventory description. This would allow the use of monomers later at greater than 2 percent.

In the proposed and final PMN rules, EPA consistently required all monomers and other reactants to be described. (See the proposed PMN forms, published in the Federal Register of January 10, 1979 (44 FR 2286) and October 10, 1979 (44 FR 59791).) However, while monomers and reactants used at or below 2 percent by weight must be reported in the PMN, submitters have the option, as they did for the initial Inventory, of either including these substances in the polymer description or excluding them from the description for the purposes of listing on the Inventory. In the final PMN form, the submitter may exercise this option by marking the appropriate "Identity" column in the polymer identification section. (All monomers and other reactants used at greater than 2 percent are automatically included in the polymer name on the Inventory.) As for the initial Inventory, if a monomer or other reactant is not included in the Inventory description, that monomer cannot later be used at greater than 2 percent in the polymer.

In a letter dated July 27, 1983, SPI asked EPA to clarify the effect of changes in chemical identity information after the PMN review period but before a substance is added to the Inventory. As explained above, polymers are identified for Inventory purposes by: (1) All monomers and other reactants used at greater than 2 percent, and (2) at the choice of the manufacturer, monomers and other reactants used at 2 percent or less. If any monomers or other reactants included in the Inventory polymer description are eliminated before the material is added to the Inventory, a new PMN must be submitted, unless that polymer description is already included on the Inventory. If any reactants not included in the description are used at greater then 2 percent, a new PMN must also be submitted. However, the manufacturer may use new monomers or other reactants at less than 2 percent or new starting materials not incorporated into the polymer structure at any percent without notifying EPA.

Therefore, in deciding whether or not to describe a polymer on the Inventory by including monomers and other reactants used at less than 2 percent, submitters should be aware that, if they do not include the monomer and other reactants in the name listed on the Inventory, they will not be able to increase their level above 2 percent without submitting an additional PMN. On the other hand, if the monomers or other reactants are included in the Inventory name, they may be used at levels greater than 2 percent, but they may not be eliminated completely unless the manufacturer first submits a PMN.

The phrase "monomers and other reactants" applies to those reactive agents that are used intentionally to become chemically part of the polymer composition. These reactive agents include all monomers, e.g., vinyl chloride, acrylamide, terephthalic acid, and any other reactive agents that are intended to be incorporated into the polymer. Reactants other than monomers include crosslinking agents, chain-terminating agents, free radical initiators, and any other reactant which is intended to be incorporated into the structure of the polymer. This may include such substances as monohydric alcohols, e.g., methanol, and monofunctional amines, e.g., butyl amine, and acids or bases used to form a salt of the polymer.

SPI and others have indicated that in some cases it may be difficult for a manufacturer to determine whether a starting material—particularly a starting material used at less than 2 percent—is incorporated into the final polymer. EPA does not expect manufacturers to conduct a chemical analysis of the polymer to determine its exact composition for the purpose of complying with these requirements. Instead, substances should be listed in Part I(B)(2)(b) of the form only if they are intended to become incorporated into the polymer structure. If the manufacturer does not intend for the starting material to be incorporated into the polymer, it does not have to be listed in this section. For example, a starting material should not be listed in this section if it serves only to influence polymer formation without becoming a part of the new chemical substance, or if it is not intended to become part of the substance but is inadvertently incorporated into the polymer's structure. These materials, however, must be identified in other sections of the form.

Agents such as nonreactive surfactants, solvents, and catalysts and cocatalysts may be used during the manufacture of the polymer. If these agents are not intended to become chemically a part of the polymer, but if they remain in the polymer as impurities, they should be listed in Part I(B)(3) under Impurities (to the extent that it is known or reasonably ascertainable that they are present as impurities). These agents must also be identified, whether or not they may occur as polymer impurities, in the Process Description (Part I(A)(1)), which must include all feedstocks, such as reactants, solvents, catalysts, and any other substances used in the manufacture of the polymer.

In its July 27 letter, SPI expressed concern that EPA's approach to defining polymers in the PMN rule is inconsistent with Inventory reporting requirements. In particular, SPI stated that the Inventory rules required polymers to be identified only by monomers and not by "other reactants" as well. EPA, however, believes that the Inventory and PMN approaches are consistent. The Agency made it clear during the Inventory reporting period that polymer descriptions should include all reactants incorporated into the polymer structure. For example, in its standard guidance document, "Reporting for the Chemical Substance Inventory: Instructions for Reporting for the Initial Inventory" (August 1977), the Agency stated that the polymer description reported for the Inventory should identify "monomers and other reactive ingredients such as chain-transfer or crosslinking substances." Excluded from polymer descriptions were "other additives, such as emulsifiers and plasticizers, which are not chemically a part of the polymer composition" (p. 7). These are exactly the requirements for polymer identity in the PMN rule.

In addition, SPI expressed concern about the PMN rule's use of weight charged to the reactor to determine when a starting material is included in the Inventory entry. As explained in the PMN instructions manual, the "weight percent monomer or other reactant" is the weight of the material charged to the reactor expressed as a percentage of the dry weight of the manufactured polymer. Thus, the percent (by weight) of monomer A of a polymer manufactured from monomers A, B, and C is the weight of A charged to the reactor divided by the dry weight of the polymer A–B–C (times 100).

This approach is consistent with the Inventory rules and reporting instructions, which required reporting of reactants "used" at greater than 2 percent in the manufacture of the polymer. The Inventory reporting instructions clearly explain that "the 'percent (by weight)' of a monomer is the weight of the monomer charged expressed as a percentage of the weight of the polymeric chemical substance manufactured" (p. 8). EPA took this approach in developing the Inventory because of the difficulties that would be involved in requiring manufacturers to identify the exact weight percentage of different components in the final polymer. At the time, the approach was supported as reasonable by the general chemical and polymer industries.

In a letter of July 29, 1983, CMA raised a question about the requirement in Part I(B)(2)(b) of the PMN form (Polymer Identity) that submitters estimate maximum weight percent residual monomers and other reactants in new polymers and the requirement in Part I(B)(3) (Impurities) that they estimate the maximum weight percent impurities in new chemical substances. Residual monomers and other reactants reported under "Polymer Identity" do not also have to be reported under "Impurities." However, as described above, other impurities, such as residual solvents, surfactants, or catalysts not intentionally incorporated into the polymer must be reported under "Impurities." Estimates of maximum percent residual monomers and other reactants and maximum percent impurities must be provided to the extent that they are known or reasonably ascertainable.

CMA's and SPI's petitions argue that the requirements on monomers and other reactants represent substantial changes from the proposed rule and that they were not adopted with adequate notice and comments. In fact, as stated earlier, requirements concerning monomers and other reactants in EPA's January 10, 1979 and October 16, 1979 proposed PMN rules are virtually identical to those in the final rule. EPA reviewed public comments on these requirements, as well as more than three years of PMN experience, before including them in the final rule.

2. *Test data requirements.* Section 720.50(a)(3) of the rule requires that submitters provide test data on the new chemical substance in their possession or control in a "full report." The report is defined as including "experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data." These items must be provided to the extent that they are in the submitter's "possession or control"—for example, submitters are not required to provide data analyses or conclusions where they have not conducted such analyses or developed such conclusions. (Where the data appear in the open literature, the submitter need only provide a standard literature citation.) The remainder of this unit discusses in more detail the information that a full report should contain.

In considering this clarification, PMN submitters should recognize that they must provide the information only if it is in their possession or control. If certain information is not developed in the course of the test—for example, the level of impurities in the test material—the usefulness of the test results may be reduced, and their interpretation may be complicated. However, the absence of this information in the report submitted with the PMN, will not make the PMN incomplete, because it is not in the submitter's possession or control.

In general, test data should be provided in a clear and concise manner that documents conclusions drawn from the test. The amount of information appropriate will depend on the type of test and the extent to which the test methods employed are based on generally accepted, standardized methodologies. The paragraphs below provide general guidance for different types of health and environmental effects data. Companies with questions on the appropropriate format for unusual or nonstandard data are encouraged to consult with EPA individually.

For test data on standard physical or chemical properties, the property itself and a reference to the method used to make the determination, or a reference to the source from which the test method was derived, will be sufficient. Discussions of experimental methods and materials, results, data analyses, and conclusions generally would not be expected. Physical/chemical properties include such properties as absorption spectra, density, solubility, viscosity, melting point, boiling point, vapor pressure, dissociation constant, and octanol/water partition coefficient.

For environmental fate data (such as data on biodegradation or sedimentation and soil adsorption), a reference to or description of the protocol should be included. The report should also include a general description of the conditions of the test when these are not specified in the referenced protocol. For example, a report on a biodegradation study should include such information as inoculum source, adaptation possibilities, and controls employed, in addition to information on the biodegradation of the test compound during the test. The data reporting sections of EPA's "Chemical Fate Test Guidelines" (EPA 560/6–82–003, August 1982), available through the National Technical Information Service (NTIS), provide additional guidance on reporting environmental fate data. Companies submitting PMNs are not required to follow these reporting guidelines; however, their use may reduce the need for followup contact by the Agency.

A report of health or environmental effects data should include test results and a reference to or a description of the protocol used for data development. If the protocol is generally recognized—e.g., it is cited in testing guidelines published by EPA, the Organization for Economic Cooperation and Development (OECD), or the American Society for Testing and Materials (ASTM), a reference to this method or protocol will be sufficient. When recognized test protocols are referenced, the test reports should describe testing conditions, such as dose or duration, which are not specified in the guidelines. When test protocols are not referenced, the full protocol should be submitted with the test report.

For acute, subchronic, and chronic health effects reports, results should generally provide information by species, strain, sex, age, and dose level. For any test result reported as a qualitative rating, a description of or reference to the scale being used should be provided. Environmental effects studies should also summarize relevant quality control data gathered during the study. Examples of quality control data include water quality analysis, e.g., hardness, pH, temperature, and measured concentration of test material.

For further guidance on reports of health and environmental studies, submitters may consult the data reporting sections of EPA's "Health Effects Test Guidelines" (EPA 560/6–82–001) and "Environmental Effects Test Guidelines" (EPA 560–6–82–002), published in August 1982 and available through NTIS, and testing guidance published by OECD, ASTM, the National Institutes of Health (NIH), the Department of Transportation (DOT), or other agencies. As indicated above, the PMN rule does not require the use of these guidelines for test reports submitted with PMNs; however, the guidelines do suggest appropriate formats for any test data submitted to EPA.

In addition to the information described above, test reports for health and environmental effects should contain a clear description of what was tested, including chemical identity, available information on impurities (if different from that reported in the PMN), the solvent or vehicle used in the study, and the concentration of the PMN substance in the test material. When a formulated product is tested, the submitter should also identify the concentrations of the PMN substance and of solvents or other components, if available. Test reports should specify whether the testing laboratory followed Good Laboratory Practices.

PMNs must also include environmental and workplace monitoring data on the new chemical substance relevant to possible levels of human exposure or environmental release that could be associated with the manufacture, processing, distribution in commerce, use, or disposal of the substance. For example, this could include monitoring data from pilot plant operations or test marketing activities. Like other test data, these data must be provided to the extent they are in the submitter's possession or control. The data may be submitted in aggregate or summary form; underlying data, such as individual measurements, are not required.

PMN submitters should recognize that, while TSCA section 5 and the PMN rule require them to provide test data in their posession or control, they are not required to follow specific protocols or develop specific data in testing new chemical substances. The clarifications above are not intended to prescribe testing standards for new chemical substances, although EPA encourages PMN submitters to follow its guidelines, but rather to indicate the kind of data that, if available, should be included in the submitters' full test reports.

3. *Descriptions of risk assessments.* The final PMN form and the preamble to the PMN rule state that risk assessments and structure-activity relationships are "other data" under TSCA section 5(d)(1)(C). Therefore, they must be described in PMNs if they are known to or reasonably ascertainable by the submitter. In its petition, CMA asked EPA to clarify this requirement. In particular, CMA expressed the concern that the requirement would force PMN submitters to reconstruct informal, unwritten risk assessments generated during the development of a new chemical substance and to identify and assess all likely analogs of the substance. According to CMA, this would present PMN submitters with "serious practical and interpretive" problems.

The requirement to describe risks assessments and structure-activity analyses applies only to existing, written assessments of risks and analyses of structure-activity relationships. Section 720.50(b)(1) (i) and (ii) of the rule defines the "known to or reasonably ascertainable" standard, as it applies to "other data," to cover only data in the submitter's possession or control, or data known to any of his or her employees or other agents who are associated with R&D, test marketing, or commercial marketing of the new substance—that is, the requirement applies only to data that already exist. As a result, the submitter is not required to generate risk assessments or information on structure-activity relationships that do not already exist, but only to describe formal analyses already committed to writing.

PMN submitters are not required to submit the risk assessment documents or structure-activity analyses themselves. Instead, they are required to describe the contents of these documents in a technical summary. Descriptions of structure-activity analyses should include the identity of the analogs assessed (either individually or by class), structural characteristics evaluated, the health or environmental effects identified, conclusions on the applicability of the data on analogs to the PMN substance, and the bases for these conclusions. If an evaluation of structure-activity analysis did not discover any relevant information about the PMN substance, this result should also be included. Descriptions of risk assessments should include a statement of the nature and scope of the assessment and a summary of its results.

4. *Use information.* Section 720.45(f) of the rule and Part I, Section C of the form require PMN submitters to describe the intended categories of use, by function and application, to the extent that they are known or reasonably ascertainable. In its experience in the PMN program, EPA has found this information very important in estimating potential exposure and release. In the memorandum accompanying its petition, CMA expressed concern about the level of detail required on use, and asked EPA to confirm that the submitter "need not describe the substance's uses in exhaustive detail."

In its "Instructions Manual for Premanufacture Notification of New Chemical Substances," EPA provides several examples of acceptable use descriptions, including: "disperse dye for finishing polyester fibers," "surfactant in automobile spray wax," "colorant for paper and other cellulosics," and "antioxidant in fuel oils and lubricants." EPA believes that these examples clearly indicate that it neither expects nor requires exhaustively detailed use descriptions.

EPA also recognizes that in some cases PMN submitters may not know the uses of their products even to the level of detail indicated in the examples above. In these cases, the submitter is required only to identify the uses to the extent that they are known or reasonably ascertainable. For example, a manufacturer might know that it was making a surfactant for metal waxes, but might not know and could not reasonably ascertain that its customers intended to use it in automobile wax, or more particularly, automobile spray wax. In this case, a more general description would meet the rule's standard. As another example, the manufacturer might be making a surfactant that could have a wide range of applications. The PMN submitter in this case could provide a more generic description, with a few typical examples, e.g., the submitter could describe the new chemical substances as "a surfactant used in a broad range of consumer products, such as floor waxes, automobile cleaners, and general household cleaners.

EPA recognizes that a good deal of the potential burden associated with this requirement will depend on the meaning of "known or reasonably ascertainable." EPA does not expect notice submitters under this standard to obtain information that they, or "a reasonable person similarly situated," would not have obtained under normal business conditions, taking into account relevant safety and economic factors. More specifically, information derived from a knowledge of the product's chemistry (e.g., whether a dye is disperse or fiber-reactive), based on the manufacturer's knowledge of a specific customer's practices or the general practices of a processing industry (e.g., that waxes in the processing industry are typically applied by spraying), or developed by the submitter for marketing or advertising purposes should be considered reasonably ascertainable. EPA does not intend for the "reasonably ascertainable" standard to require manufacturers to contact customers solely for the purposes of completing a PMN. But where a PMN submitter routinely obtains a certain type of use information from customers as a normal part of business, he or she would be expected to provide that use information in his or her PMNs, unless the information could not be obtained in a specific case, for example, because customers considered the information confidential.

In providing use information, PMN submitters should recognize that EPA's evaluation of exposure associated with the use of the new chemical substance will be based largely on the use description in the notice. The more detailed that description, the more accurate EPA's exposure assessment will be. Therefore, while a relatively broad general use description might meet the minimum information requirements set forth in the PMN rule, it might lead to an overestimate of actual exposure levels. In the case of broad use descriptions, EPA would have to review the new chemical for all use scenarios that could be covered by the general description—some of which might involve considerably higher exposure than the uses actually intended by the manufacuturer or its customers. As a result, EPA encourages notice submitters to be as specific as reasonably possible in their use descriptions.

IV. Discussion of Other Issues

In its petition and its accompanying memorandum, CMA raised questions about the need for a mandatory PMN form, EPA's authority to declare PMNs incomplete, information requirements concerning manufacturing operations, the possibility of disclosure of confidential chemical identity contained in health and safety studies, the timing of substantiation of confidential chemical identity, and the submission of generic use information. EPA believes that the position it has taken on these issues is reasonable and correct and that the PMN rule language does not require detailed clarification. In the sections below, the Agency responds to the remaining points in the CMA petition and summarizes the reasons for the specific rule provisions. Most of these questions have been discussed more fully in the preamble to the final rule or in EPA's "Response to Comments on New Chemical Notice Requirements and Review Procedures," which is available in the public record on the PMN rule.

1. *Mandatory notice form.*

On several occasions, including its most recent petition, CMA has questioned the need for a standardized, mandatory PMN form. CMA instead recommends that EPA adopt an optional form for the guidance of submitters and that it permit the use of other forms at the submitter's discretion.

In its "Response to Comments" and elesewhere, EPA has already explained the legal basis for requiring a standardized PMN form and its need to do so. The Office of Toxic Substances (OTS) now receives, on the average, more than 100 PMNs a month, each of which must be reviewed within the statutory 90-day period. This review is now considerably complicated by the lack of a standard notice format, which makes it time-consuming and often difficult for OTS reviewers to identify critical pieces of information. Furthermore, lack of a standardized format makes it difficult to enter basic PMN data into various OTS data bases, which allows their retriveal in subsequent PMN and other reviews. As the number of PMNs increases, these problems will become more serious unless a standardized notice form is required.

2. *Incomplete notices.* CMA also expressed concern about EPA's authority to declare a PMN incomplete if the notice submitter failed to provide information required in the rule. According to CMA, "when combined with the other broad and open-ended provisions of EPA's rule, the incompleteness procedure will give EPA enormous leverage over PMN submitters," and it will result in the imposition of "onerous and unjustified" compliance burdens.

Despite these concerns, which CMA has expressed in earlier comments, EPA believes that it has clear authority to refuse to review notices that fail to meet the minimum standards of the Act, and that effective conduct of the PMN program depends on the Agency's ability to declare such notices incomplete. At the same time, however, EPA believes that it has substantially addressed CMA's concern regarding the incompleteness issue by staying or clarifying the major rule provisions identified by CMA as "broad and open-ended", the definition of "possession or control"; data requirements on "related chemicals"; and requirements concerning polymer identity, test data, risk assessments, and use. As a result, notice submitters can be assured that the incompleteness procedures will not be used in combination with "broad and open-ended" rule provisions to impose "onerous and unjustified" compliance demands.

Although EPA believes that it must have the ability to declare submissions incomplete that fail to meet the minimum standards of the rule, it anticipates having to exercise this authority only in rare cases. Since the PMN program began in July 1979, EPA has found it necessary to declare only a very few submissions incomplete out of a total of more than 2,500 notices. The Agency expects that this situation will continue once the rule is final.

In the preamble to the final rule and elsewhere, EPA has discussed the kinds of deficiencies that could lead to a determination of incompleteness.

3. *Manufacturing operations.* In the PMN form, EPA requires companies to provide certain limited information on manufacturing operations to the extent that it is known or reasonably ascertainable. For batch operations, the submitter must indicate the maximum number of kilograms per batch, the hours per batch, and the number of batches per year. For continuous operations, the submitter must indicate the maximum number of kilograms per day produced and the hours per day and days per year of operation. In addition, submitters must provide a brief description, including a diagram, of all manufacturing, processing, or use operations under their control. If any of this information is not known and not reasonably ascertainable, the submitter may simply write "NK" on the form.

In a memorandum acccompanying its petition, CMA questioned EPA's need for this information and its usefulness for the review of most new chemical substances. After reviewing its experience in the PMN program, however, EPA remains convinced that general information on manufacturing and processing operations, at the level of detail required in the current form, is essential to an effective initial review of new chemical substances. Workplace exposure and environmental release are a central part of EPA's new chemical reviews; without basic information on manufacturing and processing, it is difficult for the Agency to address these concerns adequately. At the same time, in conducting its new chemical reviews, EPA has found that companies can generally provide this information on manufacturing and processing with little difficulty. As a result, EPA does not believe that providing this information imposes a significant burden on PMN submitters.

4. *Confidential chemical identity.* In its accompanying memorandum, CMA expressed concern about the rule's provision that a chemical substance's identity is underlying data in a health and safety study of that chemical substance, regardless of whether or not the substance is identified in the study. CMA argues that, where a substance's identity is not included in a study, it should not be considered "part" of the study. This distinction is important because, under TSCA section 14(b) and the PMN rule, data underlying a health and safety study are subject to disclosure, with certain exceptions. Therefore, if a health and safety study is submitted on a new chemical substance, the substance's identity would potentially be subject to disclosure to the extent necessary to interpret the study—unless disclosure would reveal confidential information on process or mixture.

This issue was first raised in EPA's January 10, 1979, proposed PMN rules and has received considerable comment since then. Despite the concerns CMA has expressed in its petition and in earlier comments, EPA believes that its resolution of the issue in the final PMN rule appropriately balances industry's need for confidentiality and the public's need to be able to interpret test data, which underlies the purpose of section 14(b). EPA's rationale for its approach is discussed in detail in the preamble to the final rule.

As an alternative, CMA recommended that a chemical substance's identity be considered part of a health and safety study only if it is actually included in the study. EPA believes this approach is inappropriate, because the disclosure of a substance's identity would depend on the generally irrelevant question of whether or not the name of the substance, rather than a code name, was included in the report of the study submitted to EPA. Under EPA's approach in the final rule, disclosure would instead depend on the extent to which specific chemical identity was needed to interpret the health and safety study, rather than on the question of whether it was in fact included in the study. This approach was recommended by industry in previous comments on the proposed PMN rule. EPA believes this standard more effectively balances industry's and the public's interests.

5. *Timing of substantiation.* Section 720.85(b) requires that PMN submitters reassert and substantiate confidentiality claims for chemical identity at the time they file a notice of commencement of manufacture. This requirement ensures that chemical substances are listed on the TSCA Inventory by generic name only if the confidentiality claims for chemical identity are supported and if they are still applicable at the time of listing. In its accompanying memorandum, CMA questions "whether this objective justifies the time and effort required for substantiation."

EPA disagrees with CMA on this issue. The TSCA Inventory fulfills an important function as the only comprehensive public list of chemical substances in commerce in the United States, and, by listing "existing" chemical substances, it defines new chemical substances subject to PMN requirements. The presence of generic names in the Inventory appendix to a certain extent reduces its usefulness for both purposes. In particular, the use of generic names makes it more difficult for chemical companies to determine whether a given chemical substance is new and therefore subject to PMN, and it requires EPA to process and review *bona fide* requests from manufacturers asking whether their chemical substances are listed on the confidential Inventory.

For these reasons, EPA believes that it is important to ensure that generic names are entered in the Inventory appendix only when confidentiality claims for chemical identity have been supported. This will be accomplished by the requirement that companies substantiate claims for confidential chemical identity when they submit notices of commencement of manufacture. This approach is consistent with the reporting requirements for the initial Inventory, which also included substantiation of chemical identity confidentiality claims at the time a confidential substance was reported for inclusion on the Inventory. The requirement will generally impose little burden on notice submitters. As EPA's "Instructions Manual" indicates, substantiating confidentiality claims is straightforward and simple.

Although companies are required to substantiate confidentiality claims only for chemical identity at the time they submit notices of commencement, claims of confidentiality for any other information submitted in the notice of commencement should be asserted at that time.

6. *Submission of generic use description.* Section 720.87 of the rule requires PMN submitters to supply generic use descriptions for any new chemical substances whose uses they claim to be confidential. EPA issues these generic use descriptions in the Federal Register publication, required by section 5(d)(2) of TSCA, announcing the receipt of a PMN. In its accompanying memorandum, CMA expressed concern about the requirement that a generic use discription be included in PMNs, and it suggested that EPA delete this requirement from the rule.

EPA believes that this requirement should be retained and has not adopted CMA's suggestion. Section 5(d)(2) states that, within five days of receipt of a PMN, EPA must publish a Federal Register notice listing the uses or intended uses of the new chemical substance, subject to the confidentiality provisions of section 14. EPA believes that Congress intended section 14 in this context to limit public access only to the confidential aspects of a new chemical substance's uses and that, where more detailed uses are confidential, generic use descriptions must be developed to provide the public with a reasonable understanding of uses.

EPA has found it difficult to develop such use descriptions in the five days allowed by the statute, particularly because EPA staff often does not have direct knowledge of why the use is claimed confidential, or whether a particular generic use description might disclose some confidential information. Consequently, it has frequently proved necessary for EPA to consult with the PMN submitter before the Federal Register notice is published. As the number of PMN submissions grows, this task will become increasingly difficult. By requiring that PMN submitters provide generic use descriptions with their PMNs, EPA will ensure that reasonable use descriptions can be developed efficiently within the statutory time constraints. At the same time, developing this description is generally simple for the manufacturer and adds little to the costs of PMN submission.

V. Provisions Subject to Stay

As indicated above, EPA is staying certain provisions of the rule concerning the section 5(h)(3) R&D exemption, the definition of "possession or control," and data requirements on related chemicals. The Agency will be reproposing these provisions. EPA intends to issue a reproposal in the Federal Register requesting comments on specific aspects of these requirements and announcing a public meeting.

The specific provisions subject to this stay are discussed briefly below.

1. *R&D provisions.* In its petition, CMA expressed concern about four major requirements for R&D substances in the PMN rule: (1) The requirement that all persons involved in the chemical substance's lifecycle be notified of risks; (2) the requirement that companies perform an "open-ended hazard assessment" on R&D substances; (3) the recordkeeping requirements; and (4) the "retroactive" aspects of the requirements, which would apply to all new R&D substances, not simply those first manufactured after the effective date of the rule.

EPA believes that CMA has identified certain provisions in the rule concerning R&D that could, if interpreted literally, impose unnecessary burdensome requirements on manufacturers, in turn impeding chemical innovation unnecessarily. For example, EPA recognizes that the rule could be read as imposing retroactive recordkeeping requirements on R&D substances, and as requiring companies to conduct extensive, unnecessary literature searches before synthesizing laboratory substances with potential for minimal or no human or environmental exposure. EPA did not intend the R&D provisions of the rule to have either of these effects. For this reason, EPA is staying § 720.36 and § 720.78(b), the two sections of the rule that establish handling and recordkeeping requirements for exempt R&D substances. These sections of the rule will be reproposed.

The stay does not apply to the definition in § 720.3(cc) of "small quantities solely for research and development"; this definition becomes effective on October 26. The definition, which is essentially the same as the definition of R&D in the Inventory reporting rules (40 CFR Part 710), specifies which activities are exempt from PMN requirements under TSCA section 5(h)(3). In response to questions from industry, EPA is now working to clarify the line between R&D and non-R&D commercial manufacture.

Companies manufacturing or processing new chemical substances under the section 5(h)(3) exemption should understand that, regardless of this stay, they are still subject to the requirements of section 5(h)(3) that they notify persons involved in R&D of any risks they are aware of and to the requirement of the Inventory reporting rule (§ 710.2(y)) that R&D substances be used by, or directly under the supervision of, technically qualified individuals. Companies should maintain records documenting compliance with these provisions. In the absence of any documentation that a new chemical substance was manufactured solely for R&D, the Agency might conclude that the company was required to submit a PMN for that substance.

2. *Definition of possession or control.* Section 5(d)(1)(B) of TSCA requires manufacturers to submit all health and environmental effects test data on the new chemical substance in their "possession or control." In addition, § 720.3(p) defines "known or reasonably ascertainable" information to include information in a person's "possession or control." Therefore, in submitting a notice, companies must provide relevant information in their possession or control.

In its petition, CMA expressed concern about the definition of "possession or control" in § 720.3(y) of the rule. Read literally, according to CMA, the rule would require companies to conduct extensive searches of all their employee files, regardless of whether or not the employees were associated with the venture or could reasonably be assumed to have relevant data. CMA argued that this could be extremely burdensome.

In addition, CMA expressed concern about the provision that information in the submitter's possession or control includes information "in commercially available data bases to which the submitter has purchased access." CMA stated that this provision could be read as requiring submitters to conduct manual searches of material in libraries and research facilities to which they had purchased access. Other industry representatives have stated that meaningful searches of all the computerized data bases to which a company has access (which, for some companies, might mean searching as many as 60–80 data bases) could be extremely expensive, and for many data bases would yield no relevant data. For these reasons, CMA has recommended that EPA revise the definition of "possession or control" so that it does not include information in commercially available data bases, and that EPA should recognize that the submission of this information is subject to the "reasonably ascertainable" standard.

EPA believes that the issues raised by CMA and other industry representatives are sufficiently complicated to justify a further postponement of the rule's definition of "possession or control." EPA did not intend for the rule to impose the more extreme interpretations suggested by CMA—for example, that files of employees who were in no way associated with the chemical substance must be searched, or that manual searches be conducted for information in library and research facilities. Therefore, EPA is staying § 720.3(y) of the rule. Like the R&D provisions, the exact language of this definition will be revised through appropriate rulemaking procedures.

Regardless of this stay, PMN submitters are still required under section 5(d)(1)(B) of TSCA to provide health and environmental effects test data in their "possession or control." In complying with this requirement, EPA believes that manufacturers should take steps to ensure that their PMNs include relevant data from the files of employees who are: (a) Associated with R&D, test-marketing, or commercial marketing of the substance, and (b) who are reasonably likely to have such data. In other words, pending further rulemaking, EPA does not expect companies to search the files of employees not associated with the venture, or of clerical staff, graphics staff, or similar personnel who would not be expected to have any relevant data.

In addition, EPA believes that the Act requires manufacturers to take reasonable steps to ensure that their PMNs include relevant data contained in commercially available data bases to which they have purchased access. However, pending further rulemaking, EPA does not expect PMN submitters routinely to search all data bases to which they have access. For example, the rule was not intended to require companies to conduct manual searches of libraries or research facilities to determine if data on the new chemical substance were in their possession or control. Nor was it intended to require companies to search computerized data bases that were unlikely to contain "test data" or data on chemical substances, or to search data bases that the manufacturer had good reason to believe did not have data on the specific new chemical substance in question. For example, if a data base had been recently searched for a similar chemical substance, or if the company was for some other reason reasonably certain that no relevant data existed in the data base, it would not be expected to conduct the search.

3. *Data on related chemicals.* CMA also expressed concern about information requirements in § 720.50(c) concerning data on related chemicals. Under this section, PMN submitters are required to submit descriptions of unpublished data on "related chemicals," such as impurities, byproducts, degradation products, unintended reaction products, or other chemical substances or mixtures related to the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. (Submitters would not be required to describe or provide references for data on related chemicals that had been published in the open literature.) CMA stated that this requirement might be "extremely onerous," depending on the definition of "related chemicals," and that in any case it should not apply to physical-chemical property measurements and monitoring data or related chemicals.

EPA recognizes that these requirements could be read as requiring extensive monitoring and similar data on "related chemicals" that would have little if any relevance to the PMN review, and that the requirements for data on related chemicals could use further specification. Therefore, it is staying § 720.50(c) of the rule while it reveiws information requirements for related chemicals. Until this section is revised, PMN submitters should continue to follow EPA's interim PMN policies.

More generally, however, EPA rejects CMA's argument that it does not have authority under section 5 to require data (or descriptions of data) on related chemicals. According to CMA, this information cannot be required because section 5(d)(1)(B) requires submission only of data related to the effects of the new chemical substance. In fact, this section (and section 5(d)(1)(C)) requires data "related to the effect of any manufacture, processing, distribution in commerce, use, or disposal" of the new chemical substance "on health or the environment," not simply data on the substance itself. Clearly this provision requires companies to submit data on

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the potential effects of impurities in the substance, byproducts of manufacture or use, environmental transformation products, and similar related chemicals, as well as data specifically on the new chemical substance. At the same time, however, EPA agrees that monitoring and exposure data on "related chemicals" need not be submitted, unless these data are directly related to the proposed manufacture, processing, distribution, uses, or disposal of the substance (e.g., they were developed during R&D or test-marketing activities). In revising § 720.50(c) of the rule, EPA will solicit public comments on these issues and address more directly the exact information requirements on related chemicals.

In at least one respect, CMA's concerns over data requirements for related chemicals arose from a misunderstanding of the rule. CMA apparently believed that the test data themselves, rather than descriptions, were required if the data were unpublished, and that standard literature citations were required for published data. However, § 720.50(c) requires only descriptions of unpublished data on related chemicals (i.e., a description of the type of data and a summary of results), and it would not have required either published data or literature references to published data. These points will be made more explicitly in any revisions of this section.

VI. Nonsubstantive Amendments

Section 720.102(b)(1) of the May 13 rule would have required manufacturers or importers to submit a notice of commencement of manufacture or import "on the first day of such manufacture of import." In the memorandum that accompanied its petition, CMA stated that compliance with this provision may be very difficult because of "coordination difficulties or the press of other business." At the same time, EPA recognizes that, although it is important that new chemical substances be entered on the TSCA Inventory promptly after first commercial manufacture (so that subsequent manufacturers can know they are not subject to PMN requirements and to prevent unnecessary EPA review of duplicative PMNs) it makes relatively little difference whether notification of commercial manufacture occurs on the first day of manufacture or shortly thereafter. Therefore, EPA believes that companies should be allowed some latitude in when they submit notices of commencement of manufacture, and that notices submitted a short time after manufacture begins should be accepted. At the same time, however, EPA believes that companies should not be allowed to submit notices before manufacture begins; only chemical substances actually in commercial production should be added to the TSCA Inventory.

For the above reasons, EPA is amending § 720.102(b)(1) to read: "If manufacture or import for commercial purposes begins on or after the effective date of this rule, the submitter must submit the notice to EPA on, or no later than 30 calendar days after, the first day of such manufacture or import." This amendment is consistent with several comments received during the public comment period on the proposed PMN rules. This change is a technical amendment on a minor procedural aspect of this interpretive rule and does not require further notice and comment. The amendment does not work to the disadvantage of any PMN submitters, and it does not in any way impair EPA's ability to protect the public and the environment from chemical hazards. Further comment is unnecessary.

As indicated in EPA's "Instructions Manual for Premanufacture Notification of New Chemical Substances," notices of commencement of manufacture should be submitted to: Document Control Officer, Office of Toxic Substances (TS-793), U.S. Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. To ensure that notices of commencement are sent to the proper address, EPA is adding this address to the rule as § 720.102(d).

VII. Public Record

EPA has established a public record for the PMN rulemaking (docket number OPTS-50002), which is available for inspection in Rm. E-107, 401 M St. SW., Washington, D.C. 20460 from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays. Persons who do not have access to the public reading room should contact Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), at the address given earlier in this notice.

The following information related to this revision and clarification has been added to the record:

(22) USEPA-OTS, "Premanufacture Notification; Premanufacture Notice Requirements and Review Procedures," 48 FR 21722, dated May 13, 1983.

(23) Chemical Manufacturers Association (CMA), "Petition for a Stay of the Final Rule and Notice Form Implementing the Premanufacture Notification Requirements of the Toxic Substances Control Act," dated June 17, 1983.

(24) Society of the Plastics Industry, Inc. (SPI), "Petition of the Society of the Plastics Industry, Inc. for a Stay of the Final Rule and Notice Form Implementing the Premanufacture Notification Requirements of the Toxic Substances Control Act and a Request That Rule Making Be Reopened," dated June 27, 1983.

(25) USEPA-OTS, Transcript of public seminar on premanufacture notice requirements, dated June 23, 1983.

(26) SPI, Letter to M. E. Williams, Acting Director, Office of Toxic Substances, dated July 27, 1983.

(27) National Paint and Coatings Association, Letter to J. DeSantis, Office of Toxic Substances, dated July 28, 1983.

(28) American Chemical Society (ACS), Letter to D. R. Clay, Acting Assistant Administrator, Office of Pesticides and Toxic Substances, dated July 29, 1983.

(29) CMA, Letter to D. R. Clay, Acting Assistance Administrator, Office of Pesticides and Toxic Substances, dated July 29, 1983.

(30) CMA, Letter to D. R. Clay, Acting Assistance Administrator, Office of Pesticides and Toxic Substances, dated August 17, 1983.

(15 U.S.C. 2604)

List of Subjects in 40 CFR Part 720

Chemicals, Environmental protection, Premanufacture notification, Hazardous material, Recordkeeping and reporting requirements.

Dated: September 6, 1983.

William D. Ruckelshaus,

Administrator.

PART 720—[AMENDED]

Therefore, 40 CFR Part 720 is amended as follows:

§§ 720.3, 720.36, 720.50, and 720.78 [Amended]

1. The effective date of §§ 720.3(y), 720.36, 720.50(c), and 720.78(b) is hereby stayed until further notice.

2. In § 720.102 paragraph (b)(1) is revised and paragraph (d) is added to read as follows:

§ 720.102 Notice of commencement of manufacture or import.

* * * * *

(b) *When to report.* (1) If manufacture or import for commercial purposes begins on or after the effective date of this rule, the submitter must submit the notice to EPA on, or no later than 30 calendar days, after the first day of such manufacture or import.

* * * * *

(d) *Where to submit.* Notices of commencement of manufacture or import should be submitted to: Document Control Officer, Office of Toxic Substances (TS-793), U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

[FR Doc. 83-24794 Filed 9-12-83; 8:45 am]
BILLING CODE 6560-50-M