721.10012 Manganate (MnO_2^{1-}), calcium (2:1).
721.10013 Manganese yttrium oxide (Mn_2YO_5).
721.10014 Halogenated naphthalic anhydride (generic).
721.10015 Halogenated benzimidazole (generic).
721.10016 Dibenzimidazothianaphthalene (generic).
721.10017 Amine terminated bisphenol A diglycidyl ether polymer (generic).
721.10018 Calcium hydroxide oxide silicate ($Ca_6(OH)_2O_2(Si_2O_5)_3$).
721.10019 Benzoic acid, 2-chloro-5-nitro-, 1,1-dimethyl-2-oxo-2-(2-propenyloxy) ethyl ester.
721.10020 Benzoic acid, 5-amino-2-chloro-, 1,1-dimethyl-2-oxo-2-(2-propenyloxy) ethyl ester.
721.10021 Magnesium potassium titanium oxide.
721.10022 Benzenamine, *N*-phenyl-, ar′-(C_9-rich C_{8-10}-branched alkyl) derivs.
721.10023 Benzenamine, *N*-phenyl-, ar ar′-(C_9-rich C_{8-10}-branched alkyl) derivs.
721.10024 10H-Phenothiazine, ar-(C_9-rich C_{8-10}-branched alkyl) derivs.
721.10025 10H-Phenothiazine, ar, ar′-(C_9-rich C_{8-10}-branched alkyl) derivs.
721.10026 Cashew, nutshell liq., ethoxylated.
721.10027 Ethoxylated alkylsulfate, substituted alkylamine salt (generic).
721.10028 Disubstituted benzene metal salts (generic).
721.10029 Isocyanate compound, modified with methoxysilane (generic).
721.10030 Pyrimido[5,4-g]pteridine-2,4,6,8-tetramine, 4-methylbenzenesulfonate, base-hydrolyzed.
721.10031 Lithium potassium titanium oxide.
721.10032 Acrylic acid, polymer with substituted acrylamides (generic).
721.10033 Zinc, [ethanedioato(2-)-. kappa. O^1, . kappa. O^2]-.
721.10034 Substituted pyridine coupled with diazotized substituted nitrobenzonitrile, diazotized substituted benzenamine and substituted pyridinecarbonitrile (generic).
721.10035 Alkylbenzene sulfonate (generic).
721.10036 Acetaldehyde based polymer (generic).
721.10037 Complex halogenated salt of tris(ethylatedaminocarbocyclic)methane (generic).
721.10038 Trimellitic anhydride, polymer with substituted glycol, alkyl phenols and ethoxylated nonylphenol (generic).
721.10039 Diethoxybenzenamine derivative, diazotized, coupled with aminonaphthalenesulfonic acid derivative, ammonium salt (generic).
721.10040 Substituted acridine naphtha substituted benzamide (generic).
721.10041 1-Butanone, 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(4-morpholinyl)phenyl]-.
721.10042 2-Propanol, 1-[bis(2-hydroxyethyl)amino]-.
721.10043 Dineopentyl-4-substituted phthalate (generic).
721.10044 Metal oxide, modified with alkyl and vinyl terminated polysiloxanes (generic).
721.10045 Diazotized substituted heteromonocycle coupled with naphthalene sulfonic acid derivative, nickel complex, alkaline salt (generic).
721.10046 Polyaromatic amine phosphate (generic).
721.10047 Polyphosphoric acids, compds. with piperazine.
721.10048 Substituted anthraquinone (generic).
721.10049 Phenol, 4,4′- cyclohexylidene bis[2-methyl-.
721.10050 Disubstituted-*N*′- hydroxybenzenecarboximidamide (generic).
721.10051 Spiro naphthoxazine (generic).
721.10052 Aminoalkyl substituted alkylphenol (generic).
721.10053 Alkyl silane methacrylate (generic).
721.10054 Phenol, polymer with formaldehyde, 3-[(2-aminocyclohexyl)amino]-2-hydroxypropyl ethers.
721.10055 1-Propanaminium, 3-amino-*N*-(carboxymethyl)-*N*,*N*-dimethyl-, *N*-soya acyl derivs., inner salts.
721.10056 Benzenemethanaminium, *N*-(3-aminopropyl)-*N*,*N*-dimethyl-, *N*-soya acyl derivs., chlorides.

AUTHORITY: 15 U.S.C. 2604, 2607, and 2625(c).

Subpart A—General Provisions

§ 721.1 Scope and applicability.

(a) This part identifies uses of chemical substances, except for microorganisms regulated under part 725 of this chapter, which EPA has determined are significant new uses under the authority of section 5(a)(2) of the Toxic Substances Control Act. In addition, it specifies procedures for manufacturers, importers, and processors to report on those significant new uses. This subpart A contains general provisions applicable to this part. subpart B of this part identifies generic requirements for certain significant new uses cross referenced in specific provisions of subpart E of this part. subpart C of this part identifies generic reporting requirements for certain significant new uses cross referenced in specific provisions of subpart E of this part. subpart

E of this part identifies chemical substances and their significant new uses.

(b) This subpart A contains provisions governing submission and review of notices for the chemical substances and significant new uses identified in subpart E of this part. The provisions of this subpart A apply to the chemical substances and significant new uses identified in subpart E of this part, except to the extent that they are specifically modified or supplanted by specific requirements in subpart E of this part. In the event of a conflict between the provisions of this subpart A and the provisions of subpart E of this part, the provisions of subpart E of this part shall govern.

(c) The provisions of part 720 of this chapter apply to this part 721. For purposes of this part 721, wherever the phrase ''new chemical substance'' appears in part 720 of this chapter, it shall mean the chemical substance subject to this part 721. In the event of a conflict between the provisions of part 720 of this chapter and the provisions of this part 721, the provisions of this part 721 shall govern.

[53 FR 28358, July 27, 1988, as amended at 62 FR 17932, Apr. 11, 1997]

§ 721.3 Definitions.

The definitions in section 3 of the Act, 15 U.S.C. 2602, and § 720.3 of this chapter apply to this part. In addition, the following definitions apply to this part:

Acutely toxic effects A chemical substance produces acutely toxic effects if it kills within a short time period (usually 14 days):

(1) At least 50 percent of the exposed mammalian test animals following oral administration of a single dose of the test substance at 25 milligrams or less per kilogram of body weight (LD_{50}).

(2) At least 50 percent of the exposed mammalian test animals following dermal administration of a single dose of the test substance at 50 milligrams or less per kilogram of body weight (LD_{50}).

(3) At least 50 percent of the exposed mammalian test animals following administration of the test substance for 8 hours or less by continuous inhalation at a steady concentration in air at 0.5 milligrams or less per liter of air (LC_{50}).

CAS Number means Chemical Abstracts Service Registry Number assigned to a chemical substance on the Inventory.

Chemical name means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

Chemical protective clothing means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

Commercial use means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

Common name means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

Consumer means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

Consumer product means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

Customer means any person to whom a manufacturer, importer, or processor distributes any quantity of a chemical substance, or of a mixture containing the chemical substance, whether or not a sale is involved.

Director of the Office of Pollution Prevention and Toxics means the Director

of the EPA Office of Pollution Prevention and Toxics or any EPA employee delegated by the Office Director to carry out the Office Director's functions under this part.

Employer means any manufacturer, importer, processor, or user of chemical substances or mixtures.

Environmentally transformed A chemical substance is ''environmentally transformed'' when its chemical structure changes as a result of the action of environmental processes on it.

Facility means all buildings, equipment, structures, and other stationary items which are located on a single site or on contiguous or adjacent sites and which are owned or operated by the same person (or by any person which controls, is controlled by, or under common control with such person).

Identity means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

Immediate use A chemical substance is for the ''immediate use'' of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

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

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

Metalworking fluid means a liquid of any viscosity or color containing intentionally added water and used in metal machining operations for the purpose of cooling, lubricating, or rust inhibition.

MSDS means material safety data sheet, the written listing of data for the chemical substance as required under § 721.72(c).

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

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

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

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

Powder or dry solid form means a state where all or part of the substance would have the potential to become fine, loose, solid particles.

Principal importer means the first importer who, knowing that a chemical substance will be imported for a significant new use rather than manufactured in the United States, specifies the chemical substance and the amount to be imported. Only persons who are incorporated, licensed, or doing business in the United States may be principal importers.

Process for commercial purposes means the preparation of a chemical substance or mixture containing the chemical substance, after manufacture of the substance, for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture containing the chemical substance is included in this definition. If a chemical substance or mixture containing impurities is processed for commercial purposes, the impurities also are processed for commercial purposes.

Process solely for export means to process for commercial purposes solely for export from the United States

under the following restrictions on activity in the United States: Processing must be performed at sites under the control of the processor; distribution in commerce is limited to purposes of export; and the processor may not use the chemical substance except in small quantities solely for research and development.

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

Recipient means any person who purchases or otherwise obtains a chemical substance directly from a person who manufacturers, imports, or processes the substance.

Serious acute effects means human injury or human disease processes that have a short latency period for development, result from short-term exposure to a chemical substance, or are a combination of these factors and which are likely to result in death or severe or prolonged incapacitation.

Serious chronic effects means human injury or human disease processes that have a long latency period for development, result from long-term exposure to a chemical substance, or are a combination of these factors and which are likely to result in death or severe or prolonged incapacitation.

Short-term test indicative of carcinogenic potential means either any limited bioassay that measures tumor or preneoplastic induction, or any test indicative of interaction of a chemical substance with DNA (i.e., positive response in assays for gene mutation, chromosomal aberrations, DNA damage and repair, or cellular transformation).

Short-term test indicative of the potential to cause a developmentally toxic effect means either any *in vivo* preliminary development toxicity screen conducted in a mammalian species, or any *in vitro* developmental toxicity screen, including any test system other than the intact pregnant mammal, that has been extensively evaluated and judged reliable for its ability to predict the potential to cause developmentally toxic effects in intact systems across a broad range of chemicals or within a class of chemicals that includes the substance of concern.

Significant adverse environmental effects means injury to the environment by a chemical substance which reduces or adversely affects the productivity, utility, value, or function of biological, commercial, or agricultural resources, or which may adversely affect a threatened or endangered species. A substance will be considered to have the potential for significant adverse environmental effects if it has one of the following:

(1) An acute aquatic EC_{50} of 1 mg/L or less.

(2) An acute aquatic EC_{50} of 20 mg/L or less where the ratio of aquatic vertebrate 24-hour to 48-hour EC_{50} is greater than or equal to 2.0.

(3) A Maximum Acceptable Toxicant Concentration (MATC) of less than or equal to 100 parts per billion (100 ppb).

(4) An acute aquatic EC_{50} of 20 mg/L or less coupled with either a measured bioconcentration factor (BCF) equal to or greater than 1,000x or in the absence of bioconcentration data a log P value equal to or greater than 4.3.

Site means a contiguous property unit. Property divided only by a public right-of-way is one site. There may be more than one manufacturing plant on a single site.

Site-limited intermediate means an intermediate manufactured, processed, and used only within a site and not distributed in commerce other than as an impurity or for disposal. Imported intermediates cannot be ''site-limited.''

Spray application means any method of projecting a jet of vapor of finely divided liquid onto a surface to be coated; whether by compressed air, hydraulic pressure, electrostatic forces, or other methods of generating a spray.

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

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

Work area means a room or defined space in a workplace where a chemical substance is manufactured, processed,

or used and where employees are present.

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

[53 FR 28358, July 27, 1988, as amended at 54 FR 31306, July 27, 1989; 58 FR 63516, Dec. 1, 1993]

§ 721.5 Persons who must report.

(a) The following persons must submit a significant new use notice as specified under the provisions of section 5(a)(1)(B) of the Act, part 720 of this chapter, and § 721.25:

(1) A person who intends to manufacture, import, or process for commercial purposes a chemical substance identified in a specific section in subpart E of this part, and intends to engage in a significant new use of the substance identified in that section.

(2) A person who intends to manufacture, import, or process for commercial purposes a chemical substance identified in a specific section in subpart E of this part, and intends to distribute the substance in commerce. A person described in this paragraph is not required to submit a significant new use notice if that person can document one or more of the following as to each recipient of the substance from that person:

(i) That the person has notified the recipient, in writing, of the specific section in subpart E of this part which identifies the substance and its designated significant new uses.

(ii) That the recipient has knowledge of the specific section in subpart E of this part which identifies the substance and its designated significant new uses.

(iii) That the recipient cannot undertake any significant new use described in the specific section in subpart E of this part.

(b) A person described in paragraph (a)(2) of this section must submit a significant new use notice if that person has knowledge at the time of commercial distribution of the substance identified in the specific section in subpart E of this part that a recipient intends to engage in a designated significant new use of that substance without submitting a notice under this part.

(c) A person who processes a chemical substance identified in a specific section in subpart E of this part for a significant new use of that substance is not required to submit a significant new use notice if that person can document each of the following:

(1) That the person does not know the specific chemical identity of the chemical substance being processed.

(2) That the person is processing the chemical substance without knowledge that the substance is identified in subpart E of this part.

(d)(1) If at any time after commencing distribution in commerce of a chemical substance identified in a specific section in subpart E of this part a person described in paragraph (a)(2) of this section has knowledge that a recipient of the substance is engaging in a significant new use of that substance designated in that section without submitting a notice under this part, the person is required to cease supplying the chemical substance to that recipient and to submit a significant new use notice for that chemical substance and significant new use, unless the person is able to document each of the following:

(i) That the person has notified the recipient and EPA enforcement authorities (at the address in paragraph (d)(1)(iii) of this section), in writing within 15 working days of the time the person develops knowledge that the recipient is engaging in a significant new use, that the recipient is engaging in a significant new use without submitting a significant new use notice.

(ii) That, within 15 working days of notifying the recipient as described in paragraph (d)(1)(i) of this section, the person received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of the applicable section in subpart E of this part and will not engage in the significant new use.

(iii) That the person has promptly provided EPA enforcement authorities with a copy of the recepient's statement of assurance described in paragraph (d)(1)(ii) of this section. The copy must be sent to the Office of Enforcement and Compliance Assurance, Office of Compliance (2224A), U.S. Environmental Protection Agency, Ariel Rios, 1200 Pennsylvania Ave., N.W., Washington, DC, 20044.

(2) If EPA notifies the manufacturer, importer, or processor that the recipient is engaging in a significant new use after providing the statement of assurance described in paragraph (d)(1)(ii) of this section and without submitting a notice under this part, the manufacturer, importer, or processor shall immediately cease distribution to that recipient until the manufacturer, importer, or processor or the recipient has submitted a significant new use notice under this part and the notice review period has ended.

(3) If, after receiving a statement of assurance from a recipient under paragraph (d)(1)(ii) of this section, a manufacturer, importer, or processor has knowledge that the recipient is engaging in a significant new use without submitting a notice under this part, the manufacturer, importer, or processor must immediately cease distributing the substance to that recipient and notify EPA enforcement authorities at the address identified in paragraph (d)(1)(iii) of this section. The manufacturer, importer, or processor may not resume distribution to that recipient until any one of the following has occurred:

(i) The manufacturer, importer, or processor has submitted a significant new use notice under this part and the notice review period has ended.

(ii) The recipient has submitted a significant new use notice under this part and the notice review period has ended.

(iii) The manufacturer, importer, or processor has received notice from EPA enforcement authorities that it may resume distribution to that recipient.

(e) Any significant new use notice relating to import of a substance must be submitted by the principal importer.

[53 FR 28359, July 27, 1988, as amended at 60 FR 34464, July 3, 1995]

§ 721.11 Applicability determination when the specific chemical identity is confidential.

(a) A person who intends to manufacture, import, or process a chemical substance which is described by a generic chemical name is subpart E of this part may ask EPA whether the substance is subject to the requirements of this part. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture, import, or process the chemical substance for commercial purposes.

(b) To establish a *bona fide* intent to manufacture, import, or process a chemical substance, the person who intends to manufacture, import, or process the chemical substance must submit the following information in writing to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, ATTN: SNUR Bonafide submissions.

(1) The specific chemical identity of the chemical substance that the person intends to manufacture, import, or process.

(2) A signed statement that the person intends to manufacture, import, or process the chemical substance for commercial purposes.

(3) A description of the research and development activities conducted to date, and the purpose for which the person will manufacture, import, or process the chemical substance.

(4) An elemental analysis.

(5) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or, if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the substance.

(c) If an importer or processor cannot provide all the information required in paragraph (b) of this section because it is claimed as confidential business information by the importer's or processor's manufacturer or supplier, the manufacturer or supplier may supply the information directly to EPA.

(d) EPA will review the information submitted by the manufacturer, importer, or processor under paragraph (b) of this section to determine whether than person has shown a *bona fide* intent to manufacture, import, or process the chemical substance. If necessary, EPA will compare this information either to the information requested for the confidential chemical

substance under §710.7(e)(2)(v) of this chapter or the information requested under §720.85(b)(3)(iii) of this chapter.

(e) If the manufacturer, importer, or processor has shown a *bona fide* intent to manufacture, import, or process the substance and has provided sufficient unambiguous chemical identity information to enable EPA to make a conclusive determination as to the identity of the substance, EPA will inform the manufacturer, importer, or processor whether the chemical substance is subject to this part and, if so, which section in subpart E of this part applies.

(f) A disclosure to a person with a *bona fide* intent to manufacture, import, or process a particular chemical substance that the substance is subject to this part will not be considered public disclosure of confidential business information under section 14 of the Act.

(g) EPA will answer an inquiry on whether a particular chemical substance is subject to this part within 30 days after receipt of a complete submission under paragraph (b) of this section.

[53 FR 28359, July 27, 1988, as amended at 60 FR 34464, July 3, 1995; 71 FR 33641, June 12, 2006]

§ 721.20 Exports and imports.

Persons who intend to export a chemical substance identified in subpart E of this part, or in any proposed rule which would amend subpart E of this part, are subject to the export notification provisions of section 12(b) of the Act. The regulations that interpret section 12(b) appear at 40 CFR part 707. Persons who import a substance identified in a specific section in subpart E of this part are subject to the import certification requirements under section 13 of the Act, which are codified at 19 CFR 12.118 through 12.127 and 127.28. The EPA policy in support of the import certification requirements appears at 40 CFR part 707.

[53 FR 28360, July 27, 1988]

§ 721.25 Notice requirements and procedures.

(a) Each person who is required to submit a significant new use notice under this part must submit the notice at least 90 calendar days before commencing manufacture, import, or processing of a chemical substance identified in subpart E of this part for a significant new use. The submitter must comply with any applicable requirement of section 5(b) of the Act, and the notice must include the information and test data specified in section 5(d)(1) of the Act. The notice must be submitted on EPA Form 7710–25, and must comply with the requirements of part 720 of this chapter, except to the extent that they are inconsistent with this part 721.

(b) If two or more persons are required to submit a significant new use notice for the same chemical substance and significant new use identified in subpart E of this part, they may submit a joint notice to EPA. Persons submitting a joint notice must individually complete the certification section of part I of the required notification form. Persons who are required to submit individually, but elect to submit jointly, remain individually liable for the failure to submit required information which is known to or reasonably ascertainable by them and test data in their possession or control.

(c) EPA will process the notice in accordance with the procedures of part 720 of this chapter, expect to the extent they are inconsistent with this part 721.

(d) Any person submitting a significant new use notice in response to the requirements of this part 721 shall not manufacture, import, or process a chemical substance identified in subpart E of this part for a significant new use until the notice review period, including all extensions and suspensions, has expired.

[53 FR 28360, July 27, 1988, as amended at 60 FR 16311, Mar. 29, 1995]

§ 721.30 EPA approval of alternative control measures.

(a) In certain sections of subpart E of this part, significant new uses for the identified substances are described as the failure to establish and implement programs providing for the use of either: specific measures to control worker exposure to or release of substances which are identified in such

sections, or alternative measures to control worker exposure or environmental release which EPA has determined provide substantially the same degree of protection as the specified control measures. Persons who manufacture, import, or process a chemical substance identified in such sections and who intend to employ alternative measures to control worker exposure or environmental release must submit a request to EPA for a determination of equivalency before commencing manufacture, import, or processing involving the alternative control measures.

(b) A request for a determination of equivalency must be submitted in writing to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; ATTN: SNUR Equivalency Determination, and must contain:

(1) The name of the submitter.

(2) The specific chemical identity of the substance.

(3) The citation for the specific section in subpart E of this part which pertains to the substance for which the request is being submitted.

(4) A detailed description of the activities involved.

(5) The specifications of the alternative worker exposure control measures or environmental release control measures.

(6) An analysis justifying why such alternative control measures provide substantially the same degree of protection as the specific control measures identified in the specific section in subpart E of this part which pertains to the substance for which the request is being submitted.

(7) The data and information described in §720.50 (a) and (b) of this chapter unless such data and information have already been submitted to the Office of Pollution Prevention and Toxics, EPA.

(c) Requests for determinations of equivalency will be reviewed by EPA within 45 days. Determinations under this paragraph will be made by the Director, Office of Pollution Prevention and Toxics, or designee. Notice of the results of such determinations will be mailed to the submitter.

(d) If EPA notifies the submitter under paragraph (c) of this section that EPA has determined that the alternative control measures provide substantially the same degree of protection as the specified control measures identified in the specified section of subpart E of this part which pertains to the substance for which the request is being submitted, the submitter may commence manufacture, import, or processing in accordance with the specifications for alternative worker exposure control measures or environmental release control measures identified in the submitter's request, and may alter any corresponding notification to workers to reflect such alternative controls. Deviations from the activities described in the EPA notification constitute a significant new use and are subject to the requirements of this part.

[53 FR 28360, July 27, 1988, as amended at 60 FR 34464, July 3, 1995; 71 FR 33641, June 12, 2006]

§ 721.35 Compliance and enforcement.

(a) Failure to comply with any provision of this part is a violation of section 15(1) of the Act (15 U.S.C. 2614).

(b) Using for commercial purposes a chemical substance which a person knew or had reason to know was manufactured, imported, or processed in violation of this part is a violation of section 15(2) of the Act (15 U.S.C. 2614).

(c) Failure or refusal to permit access to or copying of records, as required by section 11 of the Act, is a violation of section 15(3) of the Act (15 U.S.C. 2614).

(d) Failure or refusal to permit entry or inspection, as required by section 11 of the Act, is a violation of section 15(4) of the Act.

(e) Violators of the Act or of this part may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. The submission of false or misleading information in connection with the requirement of any provision of this part may subject persons to penalties calculated as if they never filed a notice.

(f) Under the authority of sections 7 and 17 of the Act, EPA may:

(1) Seek to enjoin the manufacture, import, or processing of a chemical substance in violation of this part.

(2) Act to seize any chemical substance which is being manufactured, imported, or processed in violation of this part.

(3) Take any other appropriate action.

[53 FR 28361, July 27, 1988]

§ 721.40 Recordkeeping.

Any person subject to the requirements of this part must retain documentation of information contained in that person's significant new use notice. This documentation must be maintained for a period of 5 years from the date of the submission of the significant new use notice.

[53 FR 28361, July 27, 1988]

§ 721.45 Exemptions.

The persons identified in §721.5 are not subject to the notification requirements of §721.25 for a chemical substance identified in subpart E of this part, unless otherwise specified in a specific section in subpart E, if:

(a) The person has applied for and has been granted an exemption for test marketing the substance for a significant new use identified in subpart E of this part in accordance with section 5(h)(1) of the Act and §720.38 of this chapter.

(b) The person manufactures, imports, or processes the substance for a significant new use identified in subpart E of this part in small quantities solely for research and development in accordance with §721.47.

(c) The person has applied for and been granted an exemption under section 5(h)(5) of the Act.

(d) The person manufactures, imports, or processes the substance only as an impurity.

(e) The person manufactures, imports, or processes the substance only as a byproduct which is used only by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes.

(f) The person imports or processes the substance as part of an article.

(g) The person manufactures or processes the substance solely for export and, when distributing the substance in commerce, labels the substance in accordance with section 12(a)(1)(B) of the Act.

(h) The person submits a significant new use notice for the substance prior to the promulgation date of the section in subpart E of this part which identifies the substance, and the person receives written notification of compliance from EPA prior to the effective date of such section. The notice submitter must comply with any applicable requirement of section 5(b) of the Act. The notice must include the information and test data specified in section 5(d)(1) of the Act and must be submitted on the notice form in Appendix A to part 720 of this chapter. For purposes of this exemption, the specific section in subpart E of this part which identifies the substance and §§721.1, 721.3, 721.11, 721.35, and 721.40 apply; after the effective date of the section in subpart E of this part which identifies the substance, §721.5 applies and §721.20 continues to apply. EPA will provide the notice submitter with written notification of compliance only if one of the following occurs:

(1) EPA is unable to make the finding that the activities described in the significant new use notice will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances.

(2) EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in subpart E of this part which identifies the substance.

(i) The person is operating under the terms of a consent order issued under section 5(e) of the Act applicable to that person. If a provision of such section 5(e) order is inconsistent with a specific significant new use identified in subpart E of this part, abiding by the provision of the section 5(e) order exempts the person from submitting a significant new use notice for that specific significant new use.

[53 FR 28361, July 27, 1988]

§ 721.47 Conditions for research and development exemption.

(a) A person who manufactures, imports, or processes a chemical substance identifies in subpart E of this part for a significant new use identified in subpart E of this part is not subject to the notification requirements of § 721.25 if the following conditions are met:

(1) The person manufactures, imports, or processes the substance for the significant new use in small quantities solely for research and development.

(2) The manufacturer, importer, or processor notifies all persons in its employ or to whom it directly distributes the chemical substance, who are engaged in experimentation, research, or analysis on the chemical substance, including the manufacture, processing, use, transport, storage, and disposal of the substance associated with research and development activities, of any risk to health, identified under paragraph (b) of this section, which may be associated with the substance. The notification must be made in accordance with paragraph (c) of this section.

(3) The chemical substance is used by, or directly under the supervision of, a technically qualified individual.

(b)(1) To determine whether notification under paragraph (a)(2) of this section is required, the manufacturer, importer, or processor must review and evaluate the following information to determine whether there is reason to believe there is any risk to health which may be associated with the chemicals substance:

(i) Information in its possession or control concerning any significant adverse reaction by persons exposed to the chemical substance which may reasonably be associated with such exposure.

(ii) Information provided to the manufacturer, importer, or processor by a supplier or any other person concerning a health risk believed to be associated with the substance.

(iii) Health and environmental effects data in its possession or control concerning the substance.

(iv) Information on health effects which accompanies any EPA rule or order issued under section 4, 5, or 6 of the Act that applies to the substance and of which the manufacturer, importer, or processor has knowledge.

(2) When the research and development activity is conducted solely in a laboratory and exposure to the chemical substance is controlled through the implementation of prudent laboratory practices for handling chemical substances of unknown toxicity, and any distribution, except for purposes of disposal, is to other such laboratories for further research and development activity, the information specified in paragraph (b)(1) of this section need not be reviewed and evaluated. (For purposes of this paragraph (b)(2), a laboratory is defined as a contained research facility where relatively small quantities of chemical substances are used on a pro-production basis, and where activities involve the use of containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual).

(c)(1) The manufacturer, importer, or processor must notify the persons identified in paragraph (a)(2) of this section by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, written notification to each person potentially exposed, or any other method of notification which adequately informs persons of health risks which the manufacturer, importer, or processor has reason to believe may be associated with the substance, as determined under paragraph (b)(1) of this section.

(2) If the manufacturer, importer, or processor distributes a chemical substance manufactured, imported, or processed under this section to persons not in its employ, the manufacturer, importer, or processor must in written form:

(i) Notify those persons that the substance is to be used only for research and development purposes.

(ii) Provide the notice of health risks specified in paragraph (c)(1) of this section.

(3) The adequacy of any notification under this section is the responsibility of the manufacturer, importer, or processor.

(d) Quantities of the chemical substance, or of mixtures or articles containing the chemical substance, remaining after completion of research and development activities may be:

(1) Disposed of as a waste in accordance with applicable Federal, State, and local regulations, to the extent the disposal activity is not identified as a significant new use for the substance in subpart E of this part, or

(2) Used for a commercial purpose, to the extent the use is not identified as a significant new use of the substance in subpart E of this part.

(e)(1) Persons who manufacture, import, or process a chemical substance under this section must retain the following records:

(i) Copies of or citations to information reviewed and evaluated under paragraph (b)(1) of this section to determine the need to make any notification of risk.

(ii) Documentation of the nature and method of notification under paragraph (c)(1) of this section including copies of any labels or written notices used.

(iii) Documentation of prudent laboratory practices used instead of notification and evaluation under paragraph (b)(2) of this section.

(iv) The names and addresses of any persons other than the manufacturer, importer, or processor to whom the substance is distributed, the identity of the substance, the amount distributed, and copies of the notifications required under paragraph (c)(2) of this section.

(2) [Reserved]

[53 FR 28361, July 27, 1988, as amended at 58 FR 34204, June 23, 1993]

Subpart B—Certain Significant New Uses

SOURCE: 54 FR 31308, July 27, 1989, unless otherwise noted.

§ 721.50 Applicability.

This subpart B identifies certain significant new uses of chemical substances identified in subpart E of this part. The provisions of this subpart B apply only when referenced as applying to a chemical substance identified in subpart E of this part.

§ 721.63 Protection in the workplace.

(a) Whenever a substance is identified in subpart E of this part as being subject to this section, a significant new use of the substance is any manner or method of manufacturing, importing, or processing associated with any use of the substance without establishing a program whereby:

(1) Each person who is reasonably likely to be dermally exposed in the work area to the chemical substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne in the form listed in paragraph (a)(6) of this section, and cited in subpart E of this part for the chemical substance, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with 29 CFR 1910.132 and 1910.133.

(2) In addition to any other personal protective equipment selected in paragraph (a)(1) of this section, the following items are required:

(i) Gloves.

(ii) Full body chemical protective clothing.

(iii) Chemical goggles or equivalent eye protection.

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

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

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

testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area.

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

(4) Each person who is reasonably likely to be exposed to the chemical substance by inhalation in the work area in one or more of the forms listed in paragraph (a)(6) of this section and cited in subpart E of this part for the chemical substance, is provided with, and is required to wear, at a minimum, a NIOSH- approved respirator from one of the categories listed in paragraph (a)(5) of this section, and the respirator is used in accordance with 29 CFR 1910.134 and 30 CFR part 11.

(5) The following NIOSH approved respirators meet the minimum requirements for paragraph (a)(4) of this section:

(i) Category 19C Type C supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a full facepiece.

(ii) Category 19C Type C supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece.

(iii) Category 19C Type C supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet or tight-fitting facepiece.

(iv) Category 21C air-purifying respirator equipped with a full facepiece and high efficiency particulate filters.

(v) Category 21C powered air-purifying respirator equipped with a tight-fitting facepiece and high efficiency particulate filters.

(vi) Category 21C powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate filters.

(vii) Category 21C air-purifying respirator equipped with a high efficiency particulate filter including disposable respirators.

(viii) Category 23C air-purifying respirator equipped with a full facepiece and combination cartridges approved for paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(ix) Category 23C powered air-purifying respirator equipped with a tight-fitting facepiece and combination cartridges approved for paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(x) Category 23C powered air-purifying respirator equipped with a loose-fitting hood or helmet and combination cartridges approved for paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(xi) Category 23C air-purifying respirator equipped with combination cartridges approved for paints, lacquers, and enamels, including disposable respirators. (Approval label may preclude use for some paints, lacquers, or enamels.)

(xii) Category 23C air-purifying respirator equipped with a full facepiece and organic gas/vapor cartridges.

(xiii) Category 23C powered air-purifying respirator equipped with a tight-fitting facepiece and organic gas/vapor cartridges.

(xiv) Category 23C powered air-purifying respirator equipped with a loose-fitting hood or helmet and organic gas/vapor cartridges.

(xv) Category 23C air-purifying respirator equipped with organic gas/vapor cartridges, including disposable respirators.

(6) When cited in subpart E of this part for a substance, the following airborne form(s) of the substance apply to paragraphs (a) (1) and (4) of this section:

(i) Dust.

(ii) Mist.

(iii) Fume.

(iv) Smoke.

(v) Vapor.

(vi) Gas.

(b) If a substance identified in subpart E of this part is present in the work area only as a mixture, an employer is exempt from the provisions of

this section if the concentration of the substance in the mixture does not exceed a concentration set in subpart E of this part. The exemption does not apply if the employer has reason to believe that during intended use or processing in the work area, the substance in the mixture may be concentrated above the level set in subpart E of this part.

(c)(1) If at any time after commencing distribution in commerce of a chemical substance that is identified in subpart E of this part as subject to this section, the person has knowledge that a recipient of the substance is engaging in an activity that is not consistent with the implementation of a program specified in paragraph (a) of this section, the person is considered to have knowledge that the recipient is engaging in a significant new use and is required to follow the procedures in §721.5(d) unless the person is able to document the following:

(i) That the person has notified the recipient in writing within 15 working days of the time the person first has knowledge that the recipient is engaging in an activity that is not consistent with the implementation of a program specified in paragraph (a) of this section, and that the person has knowledge of the failure of implementation.

(ii) That within 15 working days of notifying the recipient that the recipient is engaging in an activity that is not consistent with the implementation of a program specified in paragraph (a) of this section the person has received from the recipient, in writing, a statement of assurance that the recipient has established the program required under paragraph (a) of this section, and will take appropriate measures to avoid activities that are inconsistent with implementation of the program required under paragraph (a) of this section.

(2) If, after receiving a statement of assurance from a recipient under paragraph (c)(1)(ii) of this section, a manufacturer, importer, or processor has knowledge that the recipient is engaging in an activity that is not consistent with the implementation of the program specified in paragraph (a) of this section, that person is considered to have knowledge that the person is engaging in a significant new use and is required to follow the procedures in §721.5(d).

§721.72 Hazard communication program.

Whenever a substance is identified in subpart E of this part as being subject to this section, a significant new use of that substance is any manner or method of manufacture, import, or processing associated with any use of that substance without establishing a hazard communication program as described in this section.

(a) *Written hazard communication program.* Each employer shall develop and implement a written hazard communication program for the substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The employer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The employer may rely on an existing hazard communication program, including an existing program established under the Occupational Health and Safety Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this paragraph. The written program shall include the following:

(1) A list of each substance identified in subpart E of this part as subject to this section known to be present in the work area. The list must be maintained in the work area and must use the identity provided on the appropriate MSDS for each substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas.

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

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

(b) *Labeling.* (1) Each employer shall ensure that each container of the substance in the workplace is labeled in accordance with this paragraph (b)(1).

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

(A) A statement of health hazard(s) and precautionary measure(s) for the substance, if any, identified in subpart E of this part or by the employer.

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

(C) A statement of environmental hazard(s) and precautionary measure(s) for the substance, if any, identified in subpart E of this part or by the employer.

(D) A statement of exposure and precautionary measure(s), if any, identified in subpart E of this part or by the employer.

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

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

(iv) The employer shall not remove or deface an existing label on incoming containers of the substance unless the container is immediately relabeled with the information specified in paragraph (b)(1)(i) of this section.

(2) Each employer shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this paragraph.

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

(A) The information required under paragraph (b)(1)(i) of this section.

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

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

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

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

(5) If the label or alternative form of warning is to be applied to a mixture containing a substance identified in subpart E of this part as subject to this section in combination with another substance identified in subpart E of this part and/or a substance defined as a ''hazardous chemical'' under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), the employer may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the employer determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under subpart E of this part, the employer must seek a determination of equivalency for such alternative control measures pursuant to §721.30 before prescribing them under this paragraph.

(c) *Material safety data sheets.* (1) Each employer must obtain or develop a MSDS for the substance.

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

(i) The identity used on the container label of the substance under this section, and, if not claimed confidential, the chemical and common name of the

substance. If the chemical and common name are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the substance known to the employer (such as vapor pressure, flash point).

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

(iv) The potential human and environmental hazards as specified in subpart E of this part for the substance.

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

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

(vii) Precautionary measures to control worker exposure and/or environmental release identified in subpart E of this part for the substance, or alternative control measures which EPA has determined under §721.30 provide substantially the same degree of protection as the identified control measures.

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

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

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

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

(xii) The name, address, and telephone number of the individual preparing or distributing the MSDS, or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

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

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

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

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

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

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

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

(d) *Employee information and training.* Each employer must ensure that employees are provided with information

and training on the substance identified in subpart E of this part. This information and training must be provided at the time of each employee's initial assignment to a work area containing the substance and whenever the substance subject to this section is introduced into the employee's work area for the first time.

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

(i) The requirements of this section.

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

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances identified in subpart E of this part as subject to this section, and MSDSs required by paragraph (c) of this section.

(2) Training provided to employees shall include:

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

(ii) The potential human health and environmental hazards of the substance as specified in subpart E of this part.

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

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

(e) *Low concentrations in mixtures.* If a substance identified in subpart E of this part is present in the work area only as a mixture, an employer is exempt from the provisions of this section if the concentration of the substance in the mixture does not exceed a concentration set in subpart E of this part. The exemption does not apply if the employer has reason to believe that during intended use or processing in the work area, the substance in the mixture may be concentrated above the level set in subpart E of this part.

(f) *Existing hazard communication program.* The employer need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(g) *Human health, environmental hazard, exposure, and precautionary statements.* Whenever referenced in subpart E of this part for a substance, the following human health and environmental hazard, exposure, and precautionary statements shall appear on each label as specified in paragraph (b) of this section and the MSDS as specified in paragraph (c) of this section. Additional statements may be included as long as they are true and do not alter the meaning of the required statements.

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

(i) Skin irritation.

(ii) Respiratory complications.

(iii) Central nervous system effects.

(iv) Internal organ effects.

(v) Birth defects.

(vi) Reproductive effects.

(vii) Cancer.

(viii) Immune system effects.

(ix) Developmental effects.

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

(i) Avoid skin contact.

(ii) Avoid breathing substance.

(iii) Avoid ingestion.

(iv) Use respiratory protection.

(v) Use skin protection.

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

(i) Toxic to fish.

(ii) Toxic to aquatic organisms.

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

(i) Disposal restrictions apply.

(ii) Spill clean-up restrictions apply.

(iii) Do not release to water.

(5) Each human health or environmental hazard precautionary statement identified in subpart E of this part for the label on the substance container must be followed by the statement, ''See MSDS for details.''

(h) *Human health, environmental hazard exposure and precautionary statements.* (1) Whenever referenced in subpart E of this part for a substance, the following human health, environmental hazard, exposure, and precautionary statements shall appear on each label as specified in paragraph (b) of this section. Additional statements may be included as long as they are true and do not alter the meaning of the required statements.

(i) *Precautionary statements.* (A) The health effects of this chemical substance have not been determined.

(B) When using this substance, use skin protection.

(C) Use respiratory protection when there is a reasonable likelihood of exposure in the work area from dust, mist, or smoke from spray application.

(D) Chemicals similar in structure to this substance have been found to cause cancer in laboratory animals.

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

(A) Skin irritation

(B) Respiratory complications

(C) Central nervous system effects

(D) Internal organ effects

(E) Birth defects

(F) Reproductive effects

(G) Cancer

(H) Immune system effects

(I) Developmental effects

(iii) *Human health hazard precautionary statements.* When using this substance:

(A) Avoid skin contact

(B) Avoid breathing substance

(C) Avoid ingestion

(D) Use respiratory protection

(E) Use skin protection

(iv) *Environmental hazard statements.* This substance may be:

(A) Toxic to fish

(B) Toxic to aquatic organisms

(v) *Environmental hazard precautionary statements.* Notice to Users:

(A) Disposal restrictions apply

(B) Spill clean-up restrictions apply

(C) Do not release to water.

(vi) *Additional statements.* Each human health or environmental precautionary statement identified in subpart E of this part for the label on the substance container must be followed by the statement, ''See MSDS for details.''

(2) Whenever referenced in subpart E of this part for a substance, the following human health, environmental hazard, exposure, and precautionary statements shall appear on each MSDS as specified in paragraph (c) of this section. Additional statements may be included as long as they are true and do not alter the meaning of the required statements.

(i) *Precautionary statements.* (A) The health effects of this chemical substance have not been determined.

(B) When using this substance, use skin protection.

(C) Use respiratory protection when there is a reasonable likelihood of exposure in the work area from dust, mist, or smoke from spray application.

(D) Chemicals similar in structure to this substance have been found to cause cancer in laboratory animals.

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

(A) Skin irritation

(B) Respiratory complications

(C) Central nervous system effects

(D) Internal organ effects

(E) Birth defects

(F) Reproductive effects

(G) Cancer

(H) Immune system effects

(I) Developmental effects

(iii) *Human health hazard precautionary statements.* When using this substance:

(A) Avoid skin contact

(B) Avoid breathing substance

(C) Avoid ingestion

(D) Use respiratory protection

(E) Use skin protection

(iv) *Environmental hazard statements.* This substance may be:

(A) Toxic to fish

(B) Toxic to aquatic organisms

(v) *Environmental hazard precautionary statements.* Notice to Users:

(A) Disposal restrictions apply
(B) Spill clean-up restrictions apply
(C) Do not release to water.

[54 FR 31308, July 27, 1989, as amended at 55 FR 45996, Oct. 31, 1990; 58 FR 34204, June 23, 1993]

§ 721.80 Industrial, commercial, and consumer activities.

Whenever a substance is identified in subpart E of this part as being subject to this section, a significant new use of the substance is:

(a) Use in non-enclosed processes.

(b) Any manner or method of manufacture in non-enclosed processes associated with any use.

(c) Any manner or method of processing in non-enclosed processes associated with any use.

(d) Use beyond the site of manufacture or import.

(e) Processing beyond the site of manufacture or import.

(f) Any manner or method of manufacture (excluding import) of the substance associated with any use.

(g) Use other than as an intermediate.

(h) Use other than as a site-limited intermediate.

(i) Use as an intermediate where the concentration of the intermediate substance in the product intended for distribution in commerce exceeds the concentration specified in subpart E of this part for the substance.

(j) Use other than as described in the premanufacture notice referenced in subpart E of this part for the substance.

(k) Use other than allowed by the section 5(e) consent order referenced in subpart E of this part for the substance.

(l) Non-industrial use.

(m) Commercial use.

(n) Non-commercial use.

(o) Use in a consumer product.

(p) Aggregate manufacture and importation volume for any use greater than that specified in subpart E of this part for the substance.

(q) Aggregate manufacture and importation volume for any use greater than that allowed by the section 5(e) consent order referenced in subpart E of this part for the substance.

(r) Aggregate manufacture and importation volume for any use greater than that specified in subpart E of this part for the substance unless the manufacturer or importer has submitted the results of the health or environmental effects studies identified in subpart E of this part for the substance and those studies comply with the procedures and criteria for developing and evaluating data identified in subpart E of this part for the substance.

(s) Annual manufacture and importation volume for any use greater than that specified in subpart E of this part for the substance.

(t) Annual manufacture and importation volume for any use greater than that allowed by the section 5(e) consent order referenced in subpart E of this part for the substance.

(u) Annual manufacture and importation volume for any use greater than that specified in subpart E of this part for the substance unless the manufacturer or importer has submitted the results of the health or environmental effects studies identified in subpart E of this part for the substance and those studies comply with the procedures and criteria for developing and evaluating data identified in subpart E of this part for the substance.

(v) Use in the form of:

(1) A powder.

(2) A solid.

(3) A liquid.

(4) A gas.

(w) Any manner or method of manufacture of the substance in the following form associated with any use:

(1) A powder.

(2) A solid.

(3) A liquid.

(4) A gas.

(x) Any manner or method of processing of the substance in the following form associated with any use:

(1) A powder.

(2) A solid.

(3) A liquid.

(4) A gas.

(y) Use involving an application method that generates:

(1) A vapor, mist, or aerosol.

(2) A dust.

§ 721.85 Disposal.

Whenever a substance is identified in subpart E of this part as being subject to this section, a significant new use of the substance is any method of:

(a) Disposal of the process stream associated with any use of the substance or with any manner or method of manufacturing associated with any use of the substance other than by the following. This provision does not supercede any applicable Federal, State, or local laws and regulations.

(1) Incineration.

(2) Landfill.

(3) Deep well injection.

(b) Disposal of the process stream associated with any use or with any manner or method of processing associated with any use other than by the following. This provision does not supercede any applicable Federal, State, or local laws and regulations.

(1) Incineration.

(2) Landfill.

(3) Deep well injection.

(c) Disposal of the use stream associated with any use, other than by the following. This provision does not supercede any applicable Federal, State, or local laws and regulations.

(1) Incineration.

(2) Landfill.

(3) Deep well injection.

(d) Disposal of the substance associated with any use of the substance, or with any manner or method of manufacture or processing in association with any use. This provision does not supercede any applicable Federal, State, or local laws and regulations.

§ 721.90 Release to water.

Whenever a substance is identified in subpart E of this part as being subject to this section, a significant new use of the substance is:

(a) Any predictable or purposeful release of a manufacturing stream associated with any use of the substance, from any site:

(1) Into the waters of the United States.

(2) Into the waters of the United States without application of one or more of the following treatment technologies as specified in subpart E of this part either by the discharger or, in the case of a release through publicly-owned treatment works, by a combination of treatment by the discharger and the publicly-owned treatment works:

(i) Chemical precipitation and settling.

(ii) Biological treatment (activated sludge or equivalent) plus clarification.

(iii) Steam stripping.

(iv) Resin or activated carbon adsorption.

(v) Chemical destruction or conversion.

(vi) Primary wastewater treatment.

(3) Into the waters of the United States without primary wastewater treatment, and secondary wastewater treatment as defined in 40 CFR part 133.

(4) Into the waters of the United States if the quotient from the following formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = \text{N parts per billion}$$

exceeds the level specified in subpart E of this part when calculated using the methods described in § 721.91. In lieu of calculating the above quotient, monitoring or alternative calculations may be used to predict the surface water concentration which will result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on written requests to approve monitoring procedures or alternative calculations within 90 days after such requests are received. EPA will inform submitters of the disposition of such requests in writing, and will explain the reasons therefor when they are denied.

(b) Any predictable or purposeful release of a process stream containing the substance associated with any use of the substance from any site:

(1) Into the waters of the United States.

(2) Into the waters of the United States without application of one or more of the following treatment technologies as specified in subpart E of this part either by the discharger or, in the case of a release through publicly-owned treatment works, by a combination of treatment by the discharger and the publicly-owned treatment works:

(i) Chemical precipitation and settling.

(ii) Biological treatment (activated sludge or equivalent) plus clarification.

(iii) Steam stripping.

(iv) Resin or activated carbon adsorption.

(v) Chemical destruction or conversion.

(vi) Primary wastewater treatment.

(3) Into the waters of the United States without primary wastewater treatment, and secondary wastewater treatment as defined in 40 CFR part 133.

(4) Into the waters of the United States if the quotient from the following formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = \text{N parts per billion}$$

exceeds the level specified in subpart E of this part when calculated using the methods described in § 721.91. In lieu of calculating the above quotient, monitoring or alternative calculations may be used to predict the surface water concentration which will result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on written requests to approve monitoring procedures or alternative calculations within 90 days after such requests are received. EPA will inform submitters of the disposition of such requests in writing, and will explain the reasons therefor when they are denied.

(c) Any predictable or purposeful release of a use stream containing the substance associated with any use of the substance from any site:

(1) Into the waters of the United States.

(2) Into the waters of the United States without application of one or more of the following treatment technologies as specified in subpart E of this part either by the discharger or, in the case of a release through publicly-owned treatment works, by a combination of treatment by the discharger and the publicly-owned treatment works:

(i) Chemical precipitation and settling.

(ii) Biological treatment (activated sludge or equivalent) plus clarification.

(iii) Steam stripping.

(iv) Resin or activated carbon adsorption.

(v) Chemical destruction or conversion.

(vi) Primary wastewater treatment.

(3) Into the waters of the United States without primary wastewater treatment, and secondary wastewater treatment as defined in 40 CFR part 133.

(4) Into the waters of the United States if the quotient from:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = \text{N parts per billion}$$

exceeds the level specified in subpart E of this part, when calculated using the methods described in § 721.91. In lieu of calculating the above quotient, however, monitoring or alternative calculations may be used to predict the surface water concentration expected to result from intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on written requests to approve monitoring procedures or alternative calculations within 90 days after such requests are received. EPA will inform submitters of the disposition of such requests in writing, and will explain the reasons therefor when they are denied.

§ 721.91 Computation of estimated surface water concentrations: Instructions.

These instructions describe the use of the equation specified in § 721.90(a)(4) and (b)(4) to compute estimated surface water concentrations which will result from release of a substance identified in subpart E of this part. The equation shall be computed for each site using the stream flow rate appropriate for the site according to paragraph (b) of this section, and the highest number of kilograms calculated to be released for that site on a given day according to paragraph (a) of this section. Two variables shall be considered in computing the equation, the number of kilograms released, and receiving stream flow.

(a) *Number of kilograms released.* (1) To calculate the number of kilograms of substance to be released from manufacturing, processing, or use operations, as specified in the numerator of the equation, develop a process description diagram which describes each manufacturing, processing, or use operation involving the substance. The process description must include the major unit operation steps and chemical conversions. A unit operation is a functional step in a manufacturing, processing, or use operation where substances undergo chemical changes and/or changes in location, temperature, pressure, physical state, or similar characteristics. Include steps in which the substance is formulated into mixtures, suspensions, solutions, etc.

(2) Indicate on each diagram the entry point of all feedstocks (e.g., reactants, solvents, and catalysts) used in the operation. Identify each feedstock and specify its approximate weight regardless of whether the process is continuous or batch.

(3) Identify all release points from which the substance or wastes containing the substance will be released into air, land, or water. Indicate these release points on the diagram. Do not include accidental releases or fugitive emissions.

(4) For releases identified in the diagram that are destined for water, estimate the amount of substance that will be released before the substance enters control technology. The kilograms of substance released may be estimated based on:

(i) The mass balance of the operation, i.e., totaling inputs and outputs, including wastes for each part of the process such that outputs equal inputs. The amount released to water may be the difference between the amount of the substance in the starting material (or formed in a reaction) minus the amount of waste material removed from each part of the process and not released to water and the amount of the substance in the final product.

(ii) Physical properties such as water solubility where a known volume of water being discharged is assumed to contain the substance at concentrations equal to its solubility in water. This approach is particularly useful where the waste stream results from separation of organic/water phases or filtration of the substance from an aqueous stream to be discharged.

(iii) Measurements of flow rates of the process/use stream and known concentrations of the substance in the stream.

(5) After releases of a substance to water are estimated for each operation on a site, total the releases of the substance to water from all operations at that site. The value (number of kilograms) specified in the numerator of the equation should reflect total kilograms of substance released to water per day from all operations at a single site.

(6) Use the highest expected daily release of the substance for each site.

(b) *Receiving stream flow.* (1) The receiving stream flow shall be expressed in million liters per day (MLD). The flow rate data to be used must be for the point of release on the water body that first receives release of the substance whether by direct discharge from a site, or by indirect discharge through a Publicly-Owned Treatment Works (POTW) for each site. The flow rate reported shall be the lowest 7-day average stream flow with a recurrence interval of 10 years (7-Q-10). If the 7-Q-10 flow rate is not available for the actual point of release, the stream flow rate should be used from the U.S. Geological Survey (USGS) gauging station that is nearest the point of release that is expected to have a flow rate less than or equal to the receiving stream flow at the point of release.

(2) Receiving stream flow data may be available from the National Pollutant Discharge Elimination System (NPDES) permit for the site or the POTW releasing the substance to surface water, from the NPDES permit-writing authority for the site or the POTW, or from USGS publications, such as the water-data report series.

(3) If receiving stream flow data are not available for a stream, either the value of 10 MLD or the daily flow of wastewater from the site or the POTW releasing the substance must be used as an assumed minimum stream flow. Similarly, if stream flow data are not available because the location of the point of release of the substance to surface water is a lake, estuary, bay, or ocean, then the flow rate to be used must be the daily flow of wastewater from the site or the POTW releasing the substance to surface water. Wastewater flow data may be available from the NPDES permit or NPDES authority for the site or the POTW releasing the substance to water.

Subpart C—Recordkeeping Requirements

§ 721.100 Applicability.

This subpart C identifies certain additional recordkeeping requirements applicable to manufacturers, importers, and processors of substances identified in subpart E of this part for each specific substance. The provisions of this subpart C apply only when referenced in subpart E of this part for a substance and significant new use identified in that subpart E. If the provisions in this subpart C conflict with general provisions of subpart A of this part, the provisions of this subpart C shall apply.

[54 FR 31313, July 27, 1989]

§ 721.125 Recordkeeping requirements.

At the time EPA adds a substance to subpart E of this part, EPA will specify appropriate recordkeeping requirements which correspond to the significant new use designations for the substance selected from subpart B of this part. Each manufacturer, importer, and processor of the substance shall maintain the records for 5 years from the date of their creation. In addition to the records specified in § 721.40, the records whose maintenance this section requires may include the following:

(a) Records documenting the manufacture and importation volume of the substance and the corresponding dates of manufacture and import.

(b) Records documenting volumes of the substance purchased in the United States by processors of the substance, names and addresses of suppliers, and corresponding dates of purchase.

(c) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture, importation, or processing to whom the manufacturer, importer, or processor directly sells or transfers the substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date.

(d) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required under § 721.63.

(e) Records documenting the determinations required by § 721.63(a)(3) that chemical protective clothing is impervious to the substance.

(f) Records documenting establishment and implementation of the hazard communication program required under § 721.72.

(g) Copies of labels required under § 721.72(b).

(h) Copies of material safety data sheets required under § 721.72(c).

(i) Records documenting compliance with any applicable industrial, commercial, and consumer use limitations under § 721.80.

(j) Records documenting compliance with any applicable disposal requirements under § 721.85, including the method of disposal, location of disposal sites, dates of disposal, and volume of the substance disposed. Where the estimated disposal volume is not known to or reasonably ascertainable by the manufacturer, importer, or processor, that person must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements.

(k) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitations under § 721.90.

[54 FR 31313, July 27, 1989]

Subpart D—Expedited Process for Issuing Significant New Use Rules for Selected Chemical Substances and Limitation or Revocation of Selected Significant New Use Rules

SOURCE: 54 FR 31314, July 27, 1989, unless otherwise noted.

§ 721.160 Notification requirements for new chemical substances subject to section 5(e) orders.

(a) *Selection of substances.* (1) In accordance with the expedited process specified in this section, EPA will issue significant new use notification requirements and other specific requirements for each new chemical substance that is the subject of a final order issued under section 5(e) of the Act, except for an order that prohibits manufacture and import of the substance, unless EPA determines that significant new use notification requirements are not needed for the substance.

(2) If EPA determines that significant new use notification requirements are not needed for a substance that is subject to a final order issued under section 5(e) of the Act, except for an order that prohibits manufacture or import of the substance, EPA will issue a notice in the FEDERAL REGISTER explaining why the significant new use requirements are not needed.

(b) *Designation of requirements.* (1) The significant new use notification and other specific requirements will be based on and be consistent with the provisions included in the final order issued for the substance under section 5(e) of the Act. EPA may also designate additional activities as significant new uses which will be subject to notification. Designation of additional activities as significant new uses will be done in accordance with the criteria and procedures under § 721.170, or through a separate rulemaking proceeding.

(2) Significant new use requirements and other specific requirements designated under this section will be listed in subpart E of this part. For each substance, subpart E will identify:

(i) The chemical name.

(ii) The activities designated as significant new uses.

(iii) Other specific requirements applicable to the substance, including recordkeeping requirements or any other requirements included in the final section 5(e) order.

(c) *Procedures for issuing significant new use rules.* (1) EPA will issue significant new use rules under this section by one of the following three processes: direct final rulemaking, interim final rulemaking, or notice and comment rulemaking. EPA will use the direct final rulemaking process to issue significant new use rules unless it determines that, in a particular case, one of the other processes is more appropriate.

(2) FEDERAL REGISTER documents issued to propose or establish significant new uses under this section will contain the following:

(i) The chemical identity of the substance or, if its specific identity is claimed confidential, an appropriate generic chemical name and an accession number assigned by EPA.

(ii) The premanufacture notice number.

(iii) The CAS number, where available and not claimed confidential.

(iv) A summary of EPA's findings under section 5(e)(1)(A) of the Act for the final order issued under section 5(e).

(v) Designation of the significant new uses subject to, or proposed to be subject to, notification and any other applicable requirements.

(vi) Any modifications of subpart A of this part applicable to the specific substance and significant new uses.

(vii) If the FEDERAL REGISTER document establishes a final rule, or notifies the public that a final rule will not be issued after public comment has been received, the document will describe comments received and EPA's response.

(3) *Direct final rulemaking.* (i) When EPA uses the direct final rulemaking procedure to issue a significant new use rule, it will issue a final rule in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new chemical substance.

(ii) The FEDERAL REGISTER document will state that, unless written notice is received by EPA within 30 days of publication that someone wishes to submit adverse or critical comments, the rule will be effective 60 days from the date of publication. The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the FEDERAL REGISTER, and a proposal will be published in the proposed rule section of the FEDERAL REGISTER. The proposal will establish a 30-day comment period.

(iii) If EPA, having considered any timely comments submitted in response to the proposal, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(4) *Notice and comment rulemaking.* (i) When EPA uses a notice and comment procedure to issue a significant new use rule, EPA will issue a proposal in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new chemical substance. Persons will be given 30 days to comment on whether EPA should establish notification requirements for the substance under this part.

(ii) If EPA, having considered any timely comments, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(5) *Interim final rulemaking.* (i) When EPA uses the interim final rulemaking procedure to issue a significant new use rule, EPA will issue an interim final rule in the final rule section of the FEDERAL REGISTER following its decision to develop a significant new use rule for a specific new chemical substance. The document will state EPA's reasons for using the interim final rulemaking procedure.

(A) The significant new use rule will take effect on the date of publication.

(B) Persons will be given 30 days from the date of publication to submit comments.

(ii) Interim final rules issued under this section shall cease to be in effect 180 days after publication unless, within the 180-day period, EPA issues a final rule in the FEDERAL REGISTER responding to any written comments received during the 30-day comment period specified in paragraph (c)(5)(i)(B) of this section and promulgating final significant new use notification requirements and other requirements for the substance.

(d) *Schedule for issuing significant new use rules.* (1) Unless EPA determines that a significant new use rule should not be issued under this section, EPA will issue a proposed rule, a direct final rule, or an interim final rule within 180

days of receipt of a valid notice of commencement under § 720.102 of this chapter for any substance for which the notice of commencement was received on or after October 10, 1989.

(2) Unless EPA determines that a significant new use rule should not be issued under this section, EPA will issue a proposed rule, a direct final rule, or an interim final rule within 1 year of October 10, 1989, for any substance for which the valid notice of commencement under § 720.102 of this chapter was received before October 10, 1989.

(3) If EPA receives adverse or critical significant comments following publication of a proposed or interim final rule, EPA will either withdraw the rule or issue a final rule addressing the comments received.

§ 721.170 Notification requirements for selected new chemical substances that have completed premanufacture review.

(a) *Selection of substances.* In accordance with the expedited process specified in this section, EPA may issue significant new use notification and recordkeeping requirements for any new chemical substance for which a premanufacture notice has been submitted under part 720 of this chapter if EPA determines that activities other than those described in the premanufacture notice may result in significant changes in human exposure or environmental release levels and/or that concern exists about the substance's health or environmental effects.

(b) *Concern criteria.* EPA may determine that concern exists about a substance's health or environmental effects if EPA makes any one of the following findings:

(1)(i) The substance may cause carcinogenic effects because the substance:

(A) Has been shown by valid test data to cause carcinogenic effects in humans or in at least one species of laboratory animal.

(B) Has been shown to be a possible carcinogen based on the weight of the evidence in short-term tests indicative of the potential to cause carcinogenic effects.

(C) Is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another substance that has been shown by test data to cause carcinogenic effects in humans or in at least one species of laboratory animal, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(D) Is known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be metabolized in humans or transformed in the environment to a substance which may have the potential to cause carcinogenic effects under the criteria in paragraphs (b)(1)(i) (A), (B), or (C) of this section.

(ii) No substance may be regulated based on a finding under paragraph (b)(1) of this section unless EPA has also made the finding under § 721.170(c)(2)(ii).

(2) The substance has been shown by valid test data to cause acutely toxic effects in at least one species of laboratory animal or is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another substance that has been shown by valid test data to cause acutely toxic effects in at least one species of laboratory animal, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(3) The substance may cause serious chronic effects, serious acute effects, or developmentally toxic effects under reasonably anticipated conditions of exposure because the substance:

(i) Has been shown by valid test data to cause serious chronic effects, serious acute effects, or developmentally toxic effects in humans or in at least one species of laboratory animal at dose levels that could be of concern under reasonably anticipated conditions of exposure.

(ii) Is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another chemical substance that has been shown by valid test data to cause serious chronic effects, serious

acute effects, or developmentally toxic effects in humans or in at least one species of laboratory animal at dose levels that could be of concern under reasonably anticipated conditions of exposure, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(iii) Is known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be metabolized in humans or transformed in the environment to a substance which may have the potential to cause serious chronic effects, serious acute effects, or developmentally toxic effects under the criteria in paragraph (b)(3) (i) and (ii) of this section.

(iv) Has been shown to potentially cause developmentally toxic effects based on the weight of the evidence in short-term tests indicative of the potential to cause developmentally toxic effects.

(4) The substance may cause significant adverse environmental effects under reasonably anticipated conditions of release because the substance:

(i) Has been shown by valid test data to cause significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release.

(ii) Is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another substance that has been shown by valid test data to cause significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(iii) Has been determined, based on calculations using the substance's physical and chemical properties, to be potentially able to cause significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release.

(iv) Is known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be environmentally transformed to a substance which may have the potential to cause significant adverse environmental effects under the criteria in paragraph (b)(4) (i), (ii), and (iii) of this section.

(5) Concern exists about the health or environmental effects of one or more impurities or byproducts of the substance because the impurity or byproduct meets one or more of the criteria in paragraph (b) (1) through (4) of this section and either:

(i) The impurity or byproduct is a new chemical substance and may be present in concentrations that could cause adverse health or environmental effects under reasonably anticipated conditions of exposure or release.

(ii) Reasonably anticipated manufacture, processing, or use activities involving the substance for which a premanufacture notice has been submitted may result in significantly increased human exposure to or environmental release of the impurity or byproduct compared to exposure or release levels resulting from existing activities involving the impurity or byproduct.

(c) *Designation of requirements.* (1) When EPA decides to establish significant new use reporting requirements under this section, EPA may designate as a significant new use any one or more of the activities set forth in subpart B of this part. In addition, EPA may designate specific recordkeeping requirements described under subpart C of this part that are applicable to the substance.

(2) EPA may designate as a significant new use only those activities that (i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified under paragraph (b) of this section.

(d) *Procedures for issuing significant new use rules.* (1) Significant new use requirements designated under this section will be listed in subpart E of this part. For each substance, subpart E of this part will identify:

(i) The chemical name.

(ii) The activities designated as significant new uses, which may include one or more of the activities described in paragraph (c) of this section.

(iii) Other specific requirements applicable to the substance.

(2) When EPA determines that a substance is a candidate for a significant new use rule under this section, it will notify the person that submitted the premanufacture notice for the substance no later than 7 calendar days before the expiration of the notice review period under §720.75 of this chapter. In providing this notice, EPA will describe the health or environmental concerns identified under paragraph (b) of this section and the activities under consideration for designation as significant new uses. Such notice may be by telephone, but in this event will be confirmed in writing no later than 30 days after completion of the notice review period.

(3) FEDERAL REGISTER documents issued to propose or establish significant new uses under this section will contain the following:

(i) The chemical identity of the substance or, if its specific identity is claimed confidential, an appropriate generic chemical name and an accession number assigned by EPA.

(ii) The premanufacture notice number.

(iii) The CAS number, where available and not claimed confidential.

(iv) A summary of the basis for action under this section.

(v) Designation of the significant new uses subject to, or proposed to be subject to, notification and any other applicable requirements.

(vi) Any modifications of subpart A of this part applicable to the specific substance and significant new uses.

(vii) If the FEDERAL REGISTER document establishes a final rule, or notifies the public that a final rule will not be issued after public comment has been received, the document will describe comments received and EPA's response.

(4) EPA will issue significant new use rules under this section by one of the following three processes: direct final rulemaking, interim final rulemaking, or notice and comment rulemaking. EPA will use the direct final rulemaking process to issue significant new use rules unless it determines that, in a particular case, one of the other processes is more appropriate.

(i)(A) When EPA uses the direct final rulemaking procedure to issue a significant new use rule it will issue a direct final rule in the final rule section of the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new chemical substance.

(B) The FEDERAL REGISTER document will state that, unless written notice is received by EPA within 30 days after the date of publication that someone wishes to submit adverse or critical comments, the SNUR will be effective 60 days from date of publication. The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days after the date of publication that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the FEDERAL REGISTER, and EPA will issue a proposed rule in the proposed rule section of the FEDERAL REGISTER. The proposed rule will establish a 30-day comment period.

(C) If EPA, having considered any timely comments submitted in response to the proposal, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(ii)(A) When EPA uses a notice and comment procedure to issue a significant new use rule, EPA will issue a proposed rule in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new chemical substance. Persons will be given 30 days to comment on whether EPA should establish notification requirements for the substance under this part.

(B) If EPA, having considered any timely comments, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(iii)(A) When EPA uses the interim final rulemaking procedure to issue a significant new use rule, EPA will issue an interim final rule in the final rule section of the FEDERAL REGISTER following its decision to develop a significant new use rule for a specific new chemical substance. The document will state EPA's reasons for using the interim final rulemaking procedure.

(*1*) The significant new use rule will take effect on the date of publication.

(*2*) Persons will be given 30 days from the date of publication to submit comments.

(B) An interim final rule issued under this section shall cease to be in effect 180 days after publication unless, within the 180-day period, EPA issues a final rule in the FEDERAL REGISTER responding to any written comments received during the 30-day comment period specified in paragraph (d)(4)(iii)(A)(*2*) of this section and promulgating final significant new use notification requirements and other requirements for the substance.

(e) *Schedule for issuing significant new use rules.* (1) EPA will issue a proposed rule, an interim final rule, or a direct final rule within 270 days of receipt of the notice of commencement under §720.102 of this chapter for any substance for which the notice of commencement was received on or after October 10, 1989.

(2) If EPA receives adverse or critical comments within the designated comment period following publication of a proposed rule or an interim final rule, EPA will either withdraw the rule or issue a final rule addressing the comments received.

[54 FR 31314, July 27, 1989, as amended at 60 FR 16316, Mar. 29, 1995]

§721.185 Limitation or revocation of certain notification requirements.

(a) *Criteria for modification or revocation.* EPA may at any time modify or revoke significant new use notification requirements for a chemical substance which has been added to subpart E of this part using the procedures under §721.160 or §721.170. Such action may be taken under this section if EPA makes one of the following determinations, unless other information shows that the requirements should be retained:

(1) Test data or other information obtained by EPA provide a reasonable basis for concluding that activities designated as significant new uses of the substance will not present an unreasonable risk of injury to human health or the environment.

(2) EPA has promulgated a rule under section 4 or 6 of the Act, or EPA or another agency has taken action under another law for the substance that eliminates the need for significant new use notification under section 5(a)(2) of the Act.

(3) EPA has received significant new use notices for some or all of the activities designated as significant new uses of the substance and, after reviewing such notices, concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

(4) EPA has examined new information, or has reexamined the test data or other information or analysis supporting its decision to add the substance to subpart E of this part under §721.170 and has concluded that the substance does not meet the criteria under §721.170(b).

(5) For a substance added to subpart E of this part under §721.160, EPA has examined new information, or has reexamined the test data or other information or analysis supporting its finding under section 5(e)(1)(A)(ii)(I) of the Act, and has concluded that a rational basis no longer exists for the findings that activities involving the substance may present an unreasonable risk of injury to human health or the environment required under section 5(e)(1)(A) of the Act.

(6) For a substance added to subpart E of this part under §721.160, certain activities involving the substance have been designated as significant new uses pending the completion of testing, and adequate test data developed in accordance with applicable procedures and criteria have been submitted to EPA.

(b) *Procedures for limitation or revocation.* Modification or revocation of significant new use notification requirements for a substance that has been added to subpart E of this part using the procedures described under § 721.160 or § 721.170 may occur either at EPA's initiative or in response to a written request.

(1) Any affected person may request modification or revocation of significant new use notification requirements for a substance that has been added to subpart E of this part using the procedures described in § 721.160 or § 721.170 by writing to the Director of the Office of Pollution Prevention and Toxics and stating the basis for such request. All requests should be sent to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. ATTN: Request to amend significant new use rule. The request must be accompanied by information sufficient to support the request.

(2) The Director of the Office of Pollution Prevention and Toxics will consider the request, make a determination whether to initiate rulemaking to modify the requirements, and notify the requester of that determination by certified letter. If the request is denied, the letter will explain why EPA has concluded that the significant new use notification requirements for that substance should remain in effect.

(3) If EPA concludes that significant new use notification requirements for a substance should be limited or revoked, EPA will propose the changes in the FEDERAL REGISTER, briefly describe the grounds for the action, and provide interested parties an opportunity to comment.

[54 FR 31314, July 27, 1989, as amended at 58 FR 34204, June 23, 1993; 60 FR 34464, July 3, 1995; 71 FR 33641, June 12, 2006]

Subpart E—Significant New Uses for Specific Chemical Substances

§ 721.225 2-Chloro-N-methyl-N-substituted acetamide (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance 2-chloro-*N*-methyl-*N*-substituted acetamide (PMN P-84–393) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3), (b) (concentration set at 1.0 percent), and (c).

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (b)(2), (d), (e) (concentration set at 1.0 percent), (f), (g)(1)(iv), (g)(2)(i), and (g)(2)(v). The provisions of § 721.72(d) requiring employees to be provided with information on the location and availability of a written hazard communication program and MSDSs do not apply when the written program and MSDSs are not required under § 721.72 (a) and (c), respectively. The provision of § 721.72(g) requiring placement of specific information on an MSDS does not apply when an MSDS is not required under § 721.72(c).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified § 721.80(g).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* The recordkeeping requirements as specified in § 721.125 (a) through (g) and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

[55 FR 32412, Aug. 9, 1990, as amended at 57 FR 20424, May 13, 1992. Redesignated at 58 FR 29946, May 24, 1993; 58 FR 34204, June 23, 1993]

§ 721.267 N-[2-[(substituted dinitrophenyl)azo]diallylamino-4-substituted phenyl] acetamide (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as *N*-[2-[(substituted dinitrophenyl)azo]diallylamino-4-substituted phenyl] acetamide (PMN P-95–513) is subject to reporting under this