4. Section 355.50 is amended by revising paragraphs (c)(1) and (c)(2), and in the headings for paragraphs (d)(1)(i) and (d)(1)(ii) by removing the word ''Paste'' and adding in its place the words ''Gel or paste'' to read as follows:

§ 355.50 Labeling of anticaries drug products.

* * * * *

(c) * * *

(1) *For all fluoride dentifrice (gel, paste, and powder) products.* ''Keep out of the reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center immediately.'' These warnings shall be used in place of the general warning statements required by § 330.1(g) of this chapter.

(2) *For all fluoride rinse and preventive treatment gel products.* ''Keep this and all drugs out of the reach of children. If you accidentally swallow more than used for'' (select appropriate word: ''brushing'' or ''rinsing''), ''seek professional assistance or contact a Poison Control Center immediately.'' These warnings shall be used in place of the general warning statements required by § 330.1(g) of this chapter.

* * * * *

Dated: September 30, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–25599 Filed 10–4–96; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309, 1310, 1313

[DEA NUMBER 138P]

RIN 1117–AA32

Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act (FD&C Act)

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule; withdrawal.

SUMMARY: DEA is withdrawing its rulemaking regarding Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act (FD&C Act) which was published in the Federal Register on August 7, 1996 (61 FR 40981). The final rule has been superseded by the Comprehensive Methamphetamine Control Act of 1996, which declares the final rule null and void and of no effect.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC. 20537, Telephone (202) 307–7183.

SUPPLEMENTARY INFORMATION: DEA published a notice of proposed rulemaking (NPRM) regarding Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act (FD&C Act) in the Federal Register on October 31, 1995 (60 FR 55348). The NPRM proposed certain amendments to Title 21, Code of Federal Regulations (CFR), Parts 1309, 1310, and 1313, and was open for public comment until January 2, 1996. Following the comment period, DEA published a final rulemaking on August 7, 1996 (61 FR 40981), which was to become effective on October 7, 1996. However, on September 29, 1996, Congress passed the Comprehensive Methamphetamine Control Act of 1996, which provides that ''The final rule concerning removal of exemption for certain pseudoephedrine products marketed under the Federal Food, Drug, and Cosmetic Act published in the Federal Register of August 7, 1996 (61 FR 40981–40933) is null and void and of no force or effect.'' As a result, the amendments contained in the final rule are canceled and the regulatory text of 21 CFR Parts 1309, 1310, and 1313 remains unchanged.

Accordingly, DEA's rulemaking entitled Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act (FD&C Act), published in the Federal Register as a proposed rule on October 31, 1995 (60 FR 55348) and as a final rule on August 7, 1996 (61 FR 40981), is withdrawn.

Dated: October 2, 1996.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 96–25665 Filed 10–4–96; 8:45 am]

BILLING CODE 4410–09–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[OPPTS–50617A; FRL 5396–6]

RIN 2070–AA58

Benzidine-Based Chemical Substances; Significant New Uses of Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating a significant new use rule (SNUR) under section 5(a) of the Toxic Substances Control Act (TSCA) which requires persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of certain benzidine-based chemical substances for any significant new use as described in this rule. EPA believes that this action is necessary because benzidine-based chemical substances may be hazardous to human health and that the uses governed by this rule may result in significant exposure to workers handling those substances. The required notice provides EPA with the opportunity to evaluate any intended new uses and associated activities before the benzidine-based chemical substances can be introduced into the marketplace for a significant new use, and an opportunity to protect against potentially adverse exposure before it occurs.

EFFECTIVE DATE: This rule becomes effective on November 20, 1996. Persons who begin commercial manufacture, importation, or processing of listed benzidine-based chemical substances for any significant new use listed in this rule between August 30, 1995, and November 20, 1996 must comply with the requirements of this final SNUR. See Unit VII of this preamble for more information. In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time on October 21, 1996.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxic Substances, Environmental Protection Agency, 401 M St., SW., Rm. E–545, Washington, DC 20460, Telephone: (202) 554–1404, TDD: (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: This SNUR requires persons to notify EPA at

least 90 days before commencing the manufacture, import, or processing of the benzidine-based chemical substances listed in this rule for any significant new use as described in § 721.1660(a)(2). The SNUR does not apply to uses of benzidine-based substances in existence when this SNUR was proposed which include uses as: A reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; and also for Colour Index (C.I.) Direct Red 28 (Congo Red, CAS No. 573–58–0) as an indicator dye. The required notification will provide EPA with information needed to evaluate the new use and associated activities, and an opportunity to protect against potentially adverse exposure to the chemical substance before it can occur. This rule was proposed on August 30, 1995 (60 FR 45119) (FRL–4762–4).

Regulated entities. Entities potentially regulated by this action are those which manufacture, import, or process the benzidine-based chemical substances listed in the rule for any use other than those listed in § 721.1660(a)(2). Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Manufacturers, importers, and processors of cyclic organic crudes and intermediates, and organic dyes.
Industry	Entities which plan to use the listed dyes in conjunction with apparel and other finished products made from fabrics, leather, and similar materials.
Industry	Entities which plan to use the listed dyes in conjunction with paper and allied products.
Industry	Manufacturers, importers, and processors of printing ink.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your business is regulated by this action, carefully examine the applicability criteria set forth in § 721.1660 of this rule. For questions regarding the applicability of this action to a particular entity, see ''FOR FURTHER INFORMATION CONTACT'' at the beginning of this document.

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' The Agency must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Section 5(a)(2) factors generally relate to the extent that a use changes the volume of a chemical substance's production or the type, form, magnitude, or duration of exposure to it. Once EPA determines by rule that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before manufacturing, importing, or processing the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)).

Persons subject to this SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of premanufacture notices (PMNs) under section 5(a)(1)(A) of TSCA (15 U.S.C. 2604(a)(1)(A)). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and (d)(1), the exemptions authorized by TSCA section 5 (h)(1), (2), (3), and (5), and the regulations at 40 CFR part 720. If during its review, EPA identifies concerns, regulatory action may be taken under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received a SNUN (15 U.S.C. 2604 (e), (f), 2605, 2606). If EPA does not take action, section 5(g) of TSCA requires EPA to explain in the Federal Register its reasons for not taking action (15 U.S.C. 2604(g)).

Persons who intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)). The regulations that interpret section 12(b) appear at 40 CFR part 707. Persons who intend to import a chemical substance identified in a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements, and to the regulations codified at 19 CFR 12.118 through 12.127 and 12.128. Such persons must certify that they are in compliance with TSCA requirements. The EPA rule in support of import certification appears at 40 CFR part 707.

II. Applicability of General Provisions

General regulatory provisions applicable to SNURs are codified at 40 CFR part 721, subpart A. In the Federal Register of August 17, 1988 (53 FR 31252), EPA promulgated a ''User Fee Rule'' (40 CFR part 700) under the authority of TSCA section 26(b) (15 U.S.C. 2625(b)). Provisions requiring persons submitting SNUNs to submit certain fees to EPA are discussed in detail in the Federal Register document. Interested persons should refer to 40 CFR parts 700 and 721 and the August 17, 1988 Federal Register document for further information.

III. Introduction

A. Summary

The chemical substances that are the subjects of this SNUR are certain benzidine-based chemical substance as listed in table 1 of § 721.1660.

EPA has determined that there is no ongoing manufacture, import, or processing, of the listed benzidine-based chemical substances, except for the ongoing uses of such substances in small amounts for a few, limited purposes (identified in § 721.1660(a)(2) of this rule). Because the listed benzidine-based chemical substances are currently only used for these limited purposes, EPA is concerned that any new use beyond the current ongoing limited uses would increase production volume resulting in increased potential for exposure to workers which would be significant because of their potential carcinogenicity. Therefore, under TSCA section 5(a)(2), EPA is designating any use of the listed benzidine-based chemical substances as a significant new use, other than the following ongoing uses of such chemical substances: As a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; and also for C. I. Direct Red 28 as an indicator dye.

Except for the ongoing uses listed above, this rule requires persons who intend to manufacture, import, or process the benzidine-based chemical substances listed in table 1 of § 721.1660 of this rule to notify EPA through the submission of a SNUN, at least 90 days before commencing the manufacture, importation, or processing of any of these substances for the significant new uses designated in this SNUR. The required notice provides EPA with the opportunity to evaluate the intended use, and, if necessary, to prohibit or limit that use before it occurs.

B. Final Rule—Changes From the Proposed Rule

The Agency reviewed all comments received on the proposed rule. After consideration of issues raised by the commenters, the Agency has taken the following actions:

1. Some inconsistencies in naming and inaccuracies in CAS numbers in table 1 of 40 CFR 721.1660 have been corrected.

2. Chemical substances not listed on the TSCA Inventory are no longer covered by this rule.

3. The use of C.I. Direct Red 28 (CAS No. 573–58–0) as an indicator dye and the use of benzidine-based chemical substances as an analytical standard were added to the list of uses not designated as significant new uses under this SNUR.

IV. Background Information on Benzidine-Based Chemical Substances

Based upon toxicity information on benzidine and benzidine-based dyes, the Agency is concerned that all the benzidine-based chemical substances listed in this rule may be carcinogens.

The molecule benzidine can only be isolated for commerce or use in the form of a salt. In recognition of this fact, whenever the term ''benzidine'' is used in this section of the preamble, it refers to the molecule benzidine, CAS No. 92–87–5, as well as to all benzidine salts.

Benzidine is an aromatic amine that has been used as a feedstock for production of man-made dyes since the late 1800's. Dyestuffs were among the first products of the developing chemical industry, and aromatic amines were the first synthetic chemicals found to cause cancer in humans. This was first reported in the last century, when some workers manufacturing dyes developed bladder cancer. Benzidine was subsequently found to be a potent carcinogen in humans and animals.

Several epidemiologic studies of occupationally exposed workers have demonstrated that benzidine exposure is associated with a high risk of developing bladder cancer (Ref. 1). Benzidine is classified by EPA as Group A, a human carcinogen (IRIS, 1996). Benzidine is also classified by the International Agency for Research on Cancer (IARC) as a Group 1 carcinogen, which are chemicals known to cause cancer in humans and animals (Ref. 2).

Originally, only benzidine was considered to be carcinogenic. However, studies found that dyes derived from benzidine release free benzidine via metabolic routes (Ref. 3). The dyes were predicted to be carcinogens based on these findings. Animal bioassays performed by the National Cancer Institute (NCI) in 1978 confirmed that administration of three different benzidine-based dyes each led to cancer. (Ref. 4)

EPA's hazard analysis (Ref. 5) is based on studies of tested representative benzidine-based dyes, as well as benzidine, from which they are synthesized, and to which they break down or metabolize. The overwhelming health concern for benzidine and benzidine-based dyes is for bladder cancer generally believed to be caused through any route of exposure. As of June 1974, the Occupational Safety and Health Administration (OSHA) requires that manufacture of benzidine be contained within a closed system (29 CFR 1910.1010 Benzidine). In addition, the American Conference of Governmental Industrial Hygienists (ACGIH) has classified benzidine as a ''confirmed human carcinogen'' with no Threshold Limit Value (TLV) assigned, and has recommended that ''all exposure to benzidine should be kept to an absolute minimum'' (Ref. 6).

Twelve benzidine-based dyes have been demonstrated to metabolize to benzidine in one or more of four species (Ref. 7). National Toxicology Program (NTP) cancer bioassays by the oral route in rodents using Direct Black 38 (CAS No. 1937–37–7), Direct Blue 6 (CAS No. 2602–46–2), and Direct Brown 95 (CAS No. 16071–86–6), showed statistically significantly elevated tumor incidence of the liver following oral administration. The time to tumor formation was 5 to 13 weeks. No tumors were found in the controls (Ref. 4). In response to these and other data, the National Institute for Occupational Safety and Health (NIOSH) and NCI have jointly recommended that these three dyes be handled in the workplace as if they were human carcinogens, and have suggested guidelines for minimizing employee exposure (Ref. 8).

Bioavailability studies in Rhesus monkeys, rats, and dogs revealed levels of benzidine in the urine, after the administration of the above-mentioned dyes, equivalent to the levels found after administration of a comparable volume of straight benzidine (Refs. 3 and 7). For this reason, IARC has classified these benzidine-based dyes as Group 2A chemicals, which are carcinogenic to animals and probably carcinogenic to humans (Refs. 1, 8, and 9). Given the consistent results from testing these dyes, as well as known mechanistic similarities among benzidine-based dyes, the entire class of benzidine-based dyes are expected to have a similar degree of toxicity. In addition, NIOSH has recommended that all benzidine-based dyes be recognized as potential human carcinogens, based upon the evaluation of information on the carcinogenicity and metabolism of these dyes (Ref. 10).

There are exposure issues for both the parent amines and the finished dyes. Most available exposure data are for groups of dyes, rather than for individual dyes. Inhalation, skin absorption, and ingestion are possible routes of exposure in a variety of settings where benzidine-based dyes are either manufactured or used. Benzidine and monoacetyl benzidine, a metabolite, have been found in the urine of workers making or using benzidine-based dyes in the paper, textile, leather, and dye manufacturing industries (Ref. 10). The amount of benzidine found in the urine was more than could be accounted for by only benzidine impurities in the dyes.

Exposure estimates for dyes were developed based on the result of a monitoring study conducted collaboratively by EPA and industry (Ref. 11). Using this information, and based on models from EPA and industry, exposure estimates have been calculated for those workers who weigh powder dyes in manufacturing establishments. From these estimates, EPA predicts the highest exposure would occur for workers who would manufacture benzidine-based dyes or who would weigh such dyes, and is also concerned about potential exposures to workers who would operate dyeing machinery (Ref. 11).

V. Rationale and Objectives for the Rule

To determine what would constitute a significant new use of benzidine-based chemical substances, EPA considered relevant information regarding the toxicity of the substances, likely exposure and releases associated with potential uses, and the four factors listed in TSCA section 5(a)(2). The Agency has concerns for bladder cancer in workers which is generally believed to be caused through any route of exposure to benzidine-based chemical substances (Ref. 5). EPA classified benzidine as Group A, a human carcinogen (IRIS, 1996). Benzidine has an IARC classification as a Group 1 carcinogen, which are chemicals known to cause cancer in humans and animals. IARC has also classified several benzidine-based dyes as Group 2A chemicals, which are carcinogenic to animals and probably carcinogenic to humans. The benzidine-based dyes that have not been tested are also suspected carcinogens (e.g., Ref. 10).

EPA has determined that there is no ongoing manufacture, import, or

processing, of the listed benzidine-based chemical substances, except for use in small amounts as a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; and also for C.I. Direct Red 28 as an indicator dye. EPA believes that the use of the subject benzidine-based substances for the uses designated at § 721.1660 would result in increases in production as well as the type, form, magnitude, or duration of exposure to these known or suspected carcinogens. Therefore, EPA is designating the uses at § 721.1660 as significant new uses (Ref. 12).

Based on these considerations, EPA wishes to achieve the following objectives with regard to the significant new uses that are designated in this rule. Specifically, EPA wants to ensure that it:

1. Receives notice of any company's intent to manufacture, import, or process the benzidine-based chemical substances for the significant new uses designated in this rule before that activity begins.

2. Has an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing the listed benzidine-based chemical substances for the significant new uses designated in this rule.

3. Can regulate prospective manufacturers, importers, or processors of the listed benzidine-based chemical substances before any significant new use occurs, provided that the degree of potential health risk is sufficient to warrant such regulation.

For the preceding reasons, EPA is designating any use of the benzidine-based chemical substances listed in § 721.1660, except for those uses listed in § 721.1660(a)(2), as significant new uses.

VI. Alternatives

Before promulgating this SNUR, EPA considered alternative regulatory actions for the listed benzidine-based chemical substances. It determined that the benzidine-based chemical substances listed in this rule are currently not subject to Federal notification requirements nor are they currently subject to any other Federal rules that regulate risks to human health or the environment to a sufficient extent to justify using those regulations as an alternative to this SNUR. EPA also considered the following alternative actions.

1. *Promulgate a TSCA section 8(a) reporting rule for these chemical substances.* Under such a rule, EPA could require any person to report information to the Agency when they intend to manufacture, import, or process the listed benzidine-based chemical substances, for a significant new use as listed in this rule (15 U.S.C. 2607). However, in the case of these particular chemical substances, the use of section 8(a) rather than SNUR authority would not provide the opportunity for EPA to review human and environmental risks associated with new uses of a chemical substance and, if necessary, take immediate follow-up regulatory action under TSCA section 5(e) or section 5(f) to prohibit or limit the activity before it begins. In view of the level of health concerns for the listed benzidine-based chemical substances, the Agency believes that a section 8(a) rule for those chemical substances would not meet EPA's regulatory objectives.

2. *Regulate the listed benzidine-based chemical substances under section 6 of TSCA.* EPA may regulate under section 6 if there is a reasonable basis to conclude that the manufacture, importation, processing, distribution in commerce, use, or disposal of a chemical substance or mixture ''presents or will present'' an unreasonable risk of injury to human health or the environment. A finding of unreasonable risk indicates a determination that the reduction of health or environmental risk resulting from a potential regulation outweighs the regulatory burden to society.

In the case of this rule, EPA decided that a SNUR was more appropriate than a section 6 rule because the Agency has not determined that the ongoing uses raise sufficient concerns to justify a section 6 regulation. At the same time, EPA's concerns are for potential future uses, and the notification which is required by this SNUR will be sufficient to allow the Agency to make the decisions necessary to protect against such uses.

VII. Applicability to Uses Occurring Before Effective Date of this Final Rule

EPA believes that the intent of section 5(a)(1)(B) is best served by designating a use as a significant new use as of the proposal date of this SNUR rather than as of the effective date of this final rule. If uses begun during the proposal period of a SNUR were considered ongoing, rather than new, as of the effective date, it would be difficult for EPA to establish SNUR notice requirements, because any person could defeat the SNUR by initiating the proposed significant new use before the rule became final, arguing that the use is no longer new.

Persons who began commercial manufacture, importation, or processing of the listed benzidine-based chemical substances for any significant new use listed in this rule between issuance of the proposed rule and the effective date of this SNUR must cease that activity before the effective date of this rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. If, however, persons who began commercial manufacture, importation, or processing of the chemical substances between the issuance of the proposed rule and the effective date of this SNUR meet the conditions of advance compliance as codified at § 721.45(h), those persons will be considered to have met the requirements of this final SNUR for those activities.

VIII. Response to Comments Received on Proposed Rule

The Agency received comments on the proposed rule from two businesses and two trade associations. The Agency reviewed and considered all significant comments received. These comments and EPA's responses follow:

Comment. Some of the dyes listed in the proposed rule are assigned incorrect CAS numbers and nomenclature.

Response. EPA reviewed the list of dyes in the proposed rule. Inconsistencies in naming substances were identified and corrected in table 1 in § 721.1660 of this final rule. Inaccurate CAS numbers were also identified and corrected in table 1 of this final rule for C.I. Direct Blue 2 (CAS No. 2429–73–4), C.I. Direct Brown 6 (CAS No. 2893–80–3), and C.I. Direct Brown 74 (CAS No. 8014–91–3). Additionally, chemical names were added to table 1 of this rule to futher identify substances subject to SNUR reporting. These corrections were minor in nature and did not change the types of benzidine-based dyes subject to this final SNUR.

Comment. A majority of the chemical substances listed in the proposed rule are not found on the TSCA Inventory. A SNUR for substances that are not on the TSCA Inventory is unnecessary because the ''PMN would serve the same purpose''.

Response. EPA conducted a review of the TSCA Inventory. This review revealed that 24 out of 149 benzidine-based chemical substances in the proposed SNUR were on the TSCA Inventory and the remaining substances were not. EPA has removed the substances that are not on the TSCA Inventory from the final list of

substances requiring notification of a significant new use. Those substances continue to be subject to the reporting requirements under TSCA section 5(a)(1) (15 U.S.C. 2604(a)(1)). Section 5(a)(1) requires a person who manufactures a chemical substance that is not on the Inventory, and not otherwise excluded or exempted from the requirements of section 5, to file a premanufacture notification (PMN) with EPA. When EPA proposed the SNUR it based the proposal on certain objectives that it announced in the preamble to the proposed rule (60 FR 45121, August 30, 1995). EPA has concluded that these same objectives can be met through the submission of a PMN for benzidine-based chemical substances that are not on the Inventory and requiring a SNUN in addition is not necessary.

Comment. C.I. Direct Red 28, a benzidine derivative, is used as a mineral acid indicator but was not identified in the proposed rule as an ongoing use. Also, certain uses of benzidine as an analytical laboratory standard, as with EPA Reference Method 8270, are also ongoing. These uses are similar to other ongoing uses identified in the proposed rule.

Response. EPA added the use of C.I. Direct Red 28 (CAS No. 573–58–0) as an indicator dye and the use of benzidine and benzidine-based chemical substances as an analytical standard to the list of ongoing uses based on information from commenters and EPA's Office of Solid Waste and Emergency Response (OSWER) (Benzidine SNUR Memo, 50617A). No additional ongoing uses of benzidine-based chemical substances were identified. Ongoing uses, as identified in § 721.1660(a)(2) of this final rule, are not subject to SNUR reporting. EPA decided to add these two uses because they are similar to other ongoing uses that were originally proposed. Like some of the proposed ongoing uses, the additional uses rely on benzidine-based substances to test for the presence of chemical substances. EPA received no objections to the inclusion of the original uses in this SNUR and has concluded that additional notice is not necessary to add these similar uses.

Comment. There are other benzidine-based dyes on the TSCA Inventory which were not listed in the proposed rule.

Response. EPA's intent is to require notification prior to the manufacture, import, or processing of all benzidine-based chemical substances on the TSCA Inventory for all non-ongoing uses. EPA conducted a thorough search of the TSCA Inventory which revealed that there are additional benzidine-based chemical substances on the TSCA Inventory that were not included in the proposed SNUR. EPA will propose a SNUR for these additional benzidine-based chemical substances in the near future.

Comment. EPA should exempt all laboratory uses of very small amounts of benzidine-based chemical substances from the SNUR where prudent laboratory practices are employed. Another comment suggested that the SNUR should not apply to laboratory uses of benzidine-based chemical substances.

Response. EPA agrees with the first comment and under existing EPA regulations, a person who manufacturers, imports, or processes a listed substance for a significant new use is not subject to SNUR notification requirements if the person is utilizing small quantities for research and development and meets the other safeguards as specified in 40 CFR 721.47. In addition, this SNUR will not cover identified laboratory uses which are ongoing (listed in § 721.1660(a)(2) of this rule). However, EPA does not agree with the second comment that all laboratory uses in general should be excluded. The purpose of the SNUR is to insure that EPA has an opportunity to review human and environmental risks associated with significant new uses of a chemical substance and, if necessary, take further action to protect against those risks. If EPA exempts all laboratory uses without any of the safeguards specified in 40 CFR 721.47, as suggested by the commenter, then persons may engage in those uses without further EPA review of these additional human and environmental exposures. The comment did not provide adequate information to allow EPA to determine the extent or possible consequences of these exposures. Given the potentially hazardous nature of benzidine-based chemical substances, EPA believes it is not appropriate to exempt all laboratory uses from the SNUR. Anyone who wishes to engage in such a new use in the future, however, may submit a significant new use notice and initiate the process for determining whether those uses pose an unreasonable risk.

Comment. The use of benzidine as a laboratory standard or an indicator dye does not constitute manufacturing, importing, or processing for a commercial purpose, i.e., for distribution in commerce. The analytical procedures, of which the benzidine is part, either consume the benzidine or produce by-products which are properly disposed. No benzidine is manufactured or processed in the course of these uses, nor is it for the purpose of distribution in commerce.

Response. EPA generally agrees with the commenter that a SNUR only regulates manufacturing and processing activities that are undertaken for commercial purposes; however, a laboratory could be engaging in regulated activities when it uses a listed benzidine-based chemical substance. TSCA provides that SNURs apply only to persons who ''manufacture or process'' subject substances (15 U.S.C. 2604(a)(1)(B)). TSCA also defines the term ''manufacture'' to include importation of as well as production (15 U.S.C. 2602(7)). TSCA further provides that SNURs only regulate manufacturing, importation, and processing activities if those activities are for ''commercial purposes'' (15 U.S.C. 5(I)). EPA interprets these provisions broadly to encompass a wide range of activities. TSCA and the SNUR regulations define manufacturing to include any activities associated with the production or importation of substances with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer or importer (40 CFR 720.3(r), defining ''manufacture or import for commercial purposes''). Processing for commercial purposes is also defined to encompass a wide range of activities (40 CFR 721.3, defining ''process for commercial purposes''). Based upon these regulations, a laboratory could be engaged in regulated activity when it uses a listed benzidine-based substance. Determining whether a laboratory is engaged in a regulated activity is very fact specific and requires an assessment of a variety of the circumstances surrounding the laboratory's activities. The commenter has not provided enough information for EPA to determine whether the activities it describes would be subject to the SNUR. Rather than speculate on hypothetical situations, EPA advises a laboratory that intends to engage in activities involving a significant new use of a listed benzidine-based chemical substance to contact EPA as specified in 40 CFR 721.11 to determine in advance whether it is subject to the SNUR. Additionally, as stated in the previous response to comment, under existing EPA regulations, a person who manufactures, imports, or processes a listed substance for a significant new use is not subject to SNUR notification requirements if the person is utilizing small quantities of research and development and meets the other

safeguards as specified in 40 CFR 721.47.

Comment. The SNUR will give an unfair advantage to foreign producers of benzidine-based chemical substances, and to those who import textiles dyed with such chemicals into the US.

Response. While EPA does not presently have a sufficient basis to support a regulatory action related to the import of articles manufactured with benzidine-based chemical substances, we have taken steps to address concerns with benzidine-based chemical substances on an international level. EPA has helped the Organization for Economic Cooperation and Development (OECD) organize an information clearinghouse so the OECD member countries can share information regarding the issues, concerns, and risk management activities surrounding benzidine-based chemical substances. EPA has also provided information to India through the U.S. Department of State. EPA plans to inform the OECD, United Nations (UN) International Program on Chemical Safety (IPCS) and the International Register of Potentially Toxic Chemicals (IRPTC) of the issuance of this SNUR so that this action might encourage other countries to examine the risks associated with the manufacture and use of benzidine-based chemical substances in their countries.

Comment. The SNUR is a ''complete product ban'', put into effect without ''sufficient analysis of the alternatives and input from the interested public''.

Response. EPA disagrees. A SNUR requires only that manufacturers, importers, and processors of the listed substances notify EPA at least 90 days before beginning any activity that EPA has designated as a ''significant new use.'' The advance notification required by the SNUR allows EPA to evaluate the proposed new use in more detail. If that evaluation reveals a concern, EPA can take action to prevent or limit unreasonable risk from the new use of the substance. Conversely if EPA decides not to take any further action, the activity may proceed.

EPA also disagrees with the comment that it failed to analyze alternatives or public input. The commenter failed to explain why it believed that there were other viable alternatives to a SNUR. Unit VI of this preamble includes EPA's analysis of alternative regulatory actions and other provisions of TSCA. EPA also discussed plans to issue a SNUR at several public meetings, and at a meeting with industry representatives held during in April, 1995 (Meeting Minutes on Benzidine-Based and Benzidine Congener-Based Dyes, 50617A). Additionally, the public submitted comments when this SNUR was proposed and EPA is responding to them in this preamble.

Comment. EPA has not addressed the issue of the ''actual risk posed by these chemicals in their current limited use''.

Response. Because this SNUR is not intended to subject ongoing uses of benzidine-based chemical substances to SNUR reporting requirements, EPA did not specifically assess risk posed by ongoing uses of benzidine-based chemical substances. Such an assessment would fall outside the scope of this rule and therefore, is unnecessary to support this rule.

Comment. The rule as proposed would not regulate significant new uses of an existing product, but rather would regulate ''old, established products and applications which are not currently used'' in the U.S.

Response. The statutory language of TSCA section 5, the legislative history, and underlying policy support EPA's conclusion that it has the authority to classify the resumption of manufacturing or processing of chemical substances as a ''significant new use.'' The term ''new'' generally encompasses uses that are occurring for the first time as well as uses that were discontinued and then occur again. See, e.g., Webster's II New Riverside University Dictionary, 1988.

The factors that TSCA requires the Administrator to consider before determining that a use is ''significant'' and ''new'' apply equally to first time and resumed uses. Section 5(a)(2) states that the Administrator's ''significant new use'' determination shall be made after considering all relevant factors including ''projected volume,'' increases in ''magnitude and duration of exposure,'' and the reasonably anticipated manner and methods of manufacturing, processing, distribution, and disposal. Both first time and resumed use may result in an increase in production volume and exposure to a chemical substance. Both types of uses also can lead to increased risks associated with manufacture, processing, distribution, and disposal.

Moreover, the legislative history of section 5 suggests that Congress intended that increased volume of manufacturing or processing would be subject to the requirements of that section. This adds further support to the conclusion that a resumption of manufacture, which necessarily entails an increase in production volume, may be classified as manufacture for a significant ''new'' use. See, e.g., H.R. Rep. No. 94–1679, 94th Cong., 2nd Sess. 66 (1976), Legislative History of the Toxic Substances Control Act 679; Senate Consideration of Conference Report on S. 3149, Sept. 28, 1976, Legislative History of the Toxic Substances Control Act at 723.

Comment. Thirty days is not a fair and reasonable comment period for such complex regulations, with extensive dockets.

Response. EPA disagrees that 30 days is not a fair and reasonable comment period. EPA allows a reasonable amount of time for comments based upon the complexity of the proposed rule and the record. Due to the relatively routine nature of SNURs and the limited nature of the material in the docket for this particular rule, the Agency believes that a 30-day comment period is reasonable in this case. EPA received no requests from the public for an extension of the comment period.

Comment. The Agency is not justified in setting retroactive dates as the effective dates for determining new uses.

Response. EPA disagrees and believes it is reasonable to make the effective date of the Agency's ''significant new use'' determination the proposal date of the rule rather than the date of the final rule. If EPA adopted the date of the final rule as the effective date, then a person could defeat the final rule simply by engaging in the proposed significant new use before the rule took effect. Further, the notification requirements for use of any listed benzidine-based chemical substance only take effect when the rule becomes final. This rule operates prospectively, not retroactively as the comment suggests.

Comment. EPA may be premature in ''extending its concern to the listed dye products'' due to SNUN requirements for test data, protocol consultation, and human exposure and environmental release data.

Response. EPA disagrees that issuing a SNUR is premature. Congress designed SNURs to allow EPA to obtain data about new uses of chemical substances that may pose significant concerns. This action is based on Agency concerns for all benzidine-based substances listed in the rule. Agency concerns for all these benzidine-based substances are based on existing carcinogenicity and exposure data of benzidine and benzidine-based substances.

As stated in Unit IX of the proposed rule (60 FR 45119, August 30, 1995), TSCA section 5 does not require persons to develop any particular test data before submitting a SNUN. Persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C.

2604(d); 40 CFR 721.25). Further, while EPA does require the submission of test data in a submitter's possession, EPA does not require the development of test data when a SNUN is submitted. Rather, EPA suggests to potential SNUR submitters the kind of data that would permit a reasoned evaluation of potential risks posed by listed benzidine-based chemical substances for an intended use. The characterization of potential health and environmental effects will help the Agency determine if regulation of the listed SNUR substance for the intended use is warranted.

Comment. According to the July 1995 American Association of Textile Chemists and Colorists (AATCC) Buyer's Guide, 15 companies were listed as distributing benzidine dyes.

Response. Of the 15 companies identified in the 1995 AATCC Buyer's Guide as selling benzidine-based chemical substances identified in this SNUR, EPA had previously contacted nine that were listed in the 1994 AATCC Buyer's Guide prior to publication of the proposed SNUR (Phone Contacts with Benzidine Dye Manufacturers and Distributors, 50617). Representatives of those nine companies confirmed that they were not manufacturing, importing, or distributing benzidine-based chemical substances identified in this SNUR. EPA representatives attempted to contact the additional six companies newly listed in the 1995 Buyer's Guide (Buyer's Guide, 50617A). Five companies indicated to EPA that they were not manufacturing, importing, or distributing benzidine-based chemical substances. EPA representatives were unable to contact the remaining company although repeated attempts were made using the information contained in the 1995 AATCC Buyer's Guide. Thus, based on the information currently available, EPA does not believe that the benzidine-based chemical substances identified in this SNUR are in commerce at this time.

IX. Test Data and Other Information

EPA recognizes that under TSCA section 5, persons are not required to develop any particular test data before submitting a significant new use notice. Rather, persons are required only to submit test data in their possession or control and to describe any other data known to, or reasonably ascertainable by, them (15 U.S.C. 2604(d); 40 CFR 721.25).

However, in view of the potential health risks that may be posed by a significant new use of the listed benzidine-based chemical substances, EPA suggests potential SNUR notice submitters include data that would permit a reasoned evaluation of risks posed by these chemical substances when utilized for an intended use. EPA currently believes that the results of the following tests could help adequately characterize possible health and environmental effects of the chemical substances: Cancer bioassays, metabolism testing, and tests for environmental fate and ecotoxicity. However, these studies may not be the only means of identifying potential risks. SNUR notices submitted without accompanying test data may increase the likelihood that EPA would take action under TSCA section 5(e).

EPA encourages persons to consult with the Agency before submitting a SNUN for benzidine-based chemical substances. As part of this optional prenotice consultation, EPA will discuss the test data it believes necessary to evaluate a significant new use of the chemical substances and advise in the selection of a protocol for testing the chemical substances. Test data should be developed according to TSCA Good Laboratory Practice Standards at 40 CFR part 792. Failure to do so may lead EPA to find such data to be insufficient to reasonably evaluate the health or environmental effects of the chemical substances.

EPA urges SNUN submitters to provide detailed information on human exposure or environmental release that may result from the significant new use of the listed benzidine-based chemical substances. In addition, EPA encourages persons to submit information on potential benefits of the chemical substances and information on risks posed by the chemical substances compared to risks posed by potential substitutes.

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUR reporting requirements for the benzidine-based chemical substances listed in this rule (Ref. 12). While there is no precise way to calculate the total annual cost of compliance with this rule, EPA estimates that the reporting cost for submitting a SNUN ranges from $7,198 to $8,170, including a $2,500 user fee. EPA believes that there will be few, if any, SNUNs submitted. Furthermore, while the expense of a notice and the uncertainty of possible EPA regulation may discourage certain innovations, that impact would be limited because such factors are unlikely to discourage an innovation that has high potential value. The Agency's economic analysis is available in the public record for this rule (OPPTS–50617A).

XI. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPPTS–50617A). The record includes basic information considered by the Agency in developing this rule and the references listed in Unit XII of this preamble.

A public version of this record, without any Confidential Business Information is available for reviewing and copying from 12 noon to 4 p.m., Monday through Friday, except legal holidays, in the TSCA Nonconfidential Information Center (NCIC), located in Rm. NE–B607, 401 M St., SW., Washington, DC.

XII. References.

(1) International Agency for Research on Cancer (IARC). IARC Monographs 1982, 29, 295–310, 311–330, 321–330).

(2) IARC Monographs, Supplement 7:123–125 (1987).

(3) Rinde, E. and Troll, W. ''Metabolic Reduction of Benzidine Azo Dyes to Benzidine in the Rhesus Monkey.'' *Journal of the National Cancer Institute* 55:181–182 (1975).

(4) National Cancer Institute (NCI). ''13-week subchronic toxicity studies of Direct Blue 6, Direct Black 38 and Direct Brown 95 dyes.'' NCI Carcinogenesis. Technical Report Series Number 108. 127p (1978).

(5) USEPA. Chemical Screening and Risk Assessment Division. Benzidine/Benzidine Congener Dyes Support Document, Ocotber 24, 1994.

(6) ACGIH. American Conference of Government Industrial Hygienists, Inc. ''Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed.'' 121-122p (1991).

(7) Lynn, R.K. et al. ''Metabolism of bisazobiphenyl dyes derived from benzidine, 3,3'-methylbenzidine and 3,3'-dimethoxybenzidine to carconogenic aromatic amines in the dog and rat.'' *Toxicology and Applied Pharmacology* 56:248–258 (1980).

(8) NIOSH/NCI, *Current Intelligence Bulletin*, 24(1,5):7–9 (1978).

(9) IARC Monographs, Supplement 7:125–126 (1987).

(10) NIOSH, Special Occupational Hazard Review for Benzidine-Based Dyes (1980).

(11) USEPA. 1990a (April). U.S. Environmental Protection Agency. Textile Dye Weighing Monitoring Study. EPA 560/5–90–009 and Supplement 560/5–90–010.

(12) USEPA. Regulatory Impact Branch, USEPA/OPPT/EETD, June 1, 1993. ''Production, Uses, and Imports of

Benzidine Based Chemicals.'' Prepared by Meridian Research, Inc.

(13) USEPA. Regulatory Impacts Branch, Economics, Exposure, and Technology Division. ''Economic Analysis to Support the Proposed SNUR for Benzidine and Benzidine-based Dyes''. May 12, 1995.

XIII. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), it has been determined that this rule is not ''significant'' and is therefore not subject to OMB review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), EPA certifies that this rule will not have a significant impact on a substantial number of small entities. This certification can be found in the docket for this rule (OPPTS–50617A). EPA has analyzed the impact of the rule on small entities based upon the criteria in the Regulatory Flexibility Act. Unit XIII.C. of this preamble and the Economic Analysis (Ref. 13) to support this SNUR (docket number OPPTS–50617A) describe the burden and costs of compliance of this rule as well as the potential impacts on small entities.

This SNUR applies to any small or large business that may wish to engage in the significant new use described in the rule. It appears that no small or large businesses are currently engaged in activity that is the subject of this rule. Although there may be some small businesses that may decide to conduct such activities in the future, it is not possible at this time to determine for certain how many, if any, there may be. Based upon past experiences, EPA expects to receive few, if any SNUNs from either small or large businesses in response to this SNUR. To date, the Agency has received less than 10 SNUNs in response to the many SNURs promulgated by EPA in the past.

There are no existing Federal rules that may duplicate, overlap, or conflict with this rule. Finally there are no significant alternatives to this rule that minimize economic impacts on small businesses and accomplish the statutory objective of insuring that EPA has an opportunity to review and evaluate the risks associated with a new use to determine whether further regulatory activity is necessary.

Information relating to this determination may be provided to the Chief Counsel for Advocacy of the Small Business Administration upon request, and is included in the docket for this rulemaking. Any comments regarding the economic impacts that this regulatory action may impose on small entities should be submitted to the Agency at the address listed above.

C. Unfunded Mandate Reform Act

This rule is not subject to the requirements of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) because this rule does not contain regulatory requirements that might significantly or uniquely affect small governments and does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. Since no current ongoing manufacture, import, or processing of the listed benzidine-based chemical substance have been identified except for uses of such substances as a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; or the use of C.I. Direct Red 28 as an indicator dye, this rule will not affect state, local, tribal governments, or the private sector. EPA expects to receive few, if any, SNUNs in response to this SNUR.

D. Executive Order 12898

Pursuant to Executive Order 12898 (59 FR 7629, February 16, 1994), entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, the Agency has considered environmental justice related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income and minority communities and does not expect any negative impacts since no current ongoing manufacture, import, or processing of the listed benzidine-based chemical substances were identified except for uses of such substances as a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; or the use of C.I. Direct Red 28 as an indicator dye. Additionally, EPA expects to receive few, if any, SNUNs in response to this SNUR.

E. Submission to Congress and the General Accounting Office

Under section 801(a)(1)(A) of the Administrative Procedure Act (APA) (5 U.S.C. 801) EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of this rule in the Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2) of the APA as amended.

F. Paperwork Reduction Act

The information collection requirements contained in this rule have already been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This activity falls under OMB control number 2070–0038 (EPA ICR No. 1188), which covers the submission of SNUNs related to existing chemicals. Specifically, persons subject to this SNUR must submit a SNUN to EPA at least 90 days before manufacturing, importing, or processing a chemical substance for any significant new use (15 U.S.C. 2604(a)(1)(B)). The SNUN allows EPA to review and evaluate the intended use and prohibit or limit that use if the degree of potential health risk is sufficient to warrant such regulation. Persons subject to this SNUR would comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under section 5(a)(1)(A) of TSCA (15 U.S.C.2604(a)(1)(A)).

Additionally, persons who intend to export a chemical substance identified in the final SNUR are subject to TSCA section 12(b) (U.S.C. 2611(b) and 40 CFR part 707). Persons who intend to import a chemical substance identified in the final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and to the regulations codified at 19 CFR 12.118 through 12.127 and 12.128. The EPA policy in support of import certification appears at 40 CFR part 707. OMB has already approved these activities under OMB Control No. 2070–0030 (EPA#795). EPA must withhold from disclosure trade secret or confidential financial or commercial information submitted under TSCA.

In submitting a SNUN, the public reporting burden for this collection of information is estimated to vary from 94 to 113 hours per response, with an average of 103 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. These hours are included and accounted for in the above-referenced existing ICR.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a

Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. EPA is also amending the table of currently approved information collection requests (ICR) control numbers issued by OMB for various regulations, which appears at 40 CFR part 9. This amendment updates the table to accurately display OMB approval of the information requirements contained in this final rule. The display of the OMB control number in this notice and its subsequent codification in the Code of Federal Regulations satisfies the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and OMB's implementing regulations at 5 CFR part 1320. The ICR was previously subject to public notice and comment prior to OMB approval. As a result, EPA finds that there is ''good cause'' under section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)) to amend this table without additional notice and comment. Due to the technical nature of the table, further notice and comment would be unnecessary.

Send comments on the burden estimates and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to Chief, Information Policy Branch (2131), U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' The ICR number must be included in any correspondence.

List of Subjects

40 CFR Part 9

Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental Protection, Chemicals, Hazardous materials, Recordkeeping and reporting requirements, Significant new uses.

Dated: September 26, 1996.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR parts 9 and 721 are amended to read as follows:

PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1321, 1326, 1330, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. Section 9.1 is amended by adding the following new entry to the table in numerical sequence to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control no.
* * *	* *
721.1660	2070–0038
* * *	* *

PART 721 —SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607 and 2625(e).

4. By adding new § 721.1660 to subpart E to read as follows:

§ 721.1660 Benzidine-based chemical substances.

(a) *Chemical substances and significant new uses subject to reporting.* (1) The benzidine-based chemical substances listed in table 1 of this section are 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 any use other than as a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; and also for Colour Index (C.I.) Direct Red 28 (Congo Red, CAS No. 573-58-0) as an indicator dye.

(b) *List of substances.* The following table 1 lists the benzidine-based chemical substances covered by this section.

Table 1.—Benzidine-Based Chemical Substances

CAS number	C.I. name	C.I. number	Chemical Name
92–87–5	Benzidine	N/A	[1,1'-Biphenyl]-4,4'-diamine
531–85–1	Benzidine • 2HCL	N/A	[1,1'-Biphenyl]-4,4'-diamine, dihydrochloride
573–58–0	C.I. Direct Red 28	22120	1-Naphthalenesulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[4-amino-, disodium salt
1937–37–7	C.I. Direct Black 38	30235	2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt
2302–97–8	C.I. Direct Red 44	22500	1-Naphthalenesulfonic acid, 8,8'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[7-hydroxy-, disodium salt
2429–73–4	C.I. Direct Blue 2	22590	2,7-Naphthalenedisulfonic acid, 5-amino-3-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-4-hydroxy-, trisodium salt

Table 1.—Benzidine-Based Chemical Substances—Continued

CAS number	C.I. name	C.I. number	Chemical Name
2429–79–0	C.I. Direct Orange 8	22130	Benzoic acid, 5-[[4'-[(1-amino-4-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
2429–81–4	C.I. Direct Brown 31	35660	Benzoic acid, 5-[[4'-[[2,6-diamino-3-[[8-hydroxy-3,6-disulfo-7-[(4-sulfo-1-naphthalenyl)azo]-2-naphthalenyl]azo]-5-methylphenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, tetrasodium salt
2429–82–5	C.I. Direct Brown 2	22311	Benzoic acid, 5-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
2429–83–6	C.I. Direct Black 4	30245	2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diamino-5-methylphenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt
2429–84–7	C.I. Direct Red 1	22310	Benzoic acid, 5-[[4'-[(2-amino-8-hydroxy-6-sulfo-1-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
2586–58–5	C.I. Direct Brown 1:2	30110	Benzoic acid, 5-[[4'-[[2,6-diamino-3-methyl-5-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
2602–46–2	C.I. Direct Blue 6	22610	2,7-Naphthalenedisulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[5-amino-4-hydroxy-, tetrasodium salt
2893–80–3	C.I. Direct Brown 6	30140	Benzoic acid, 5-[[4'-[[2,4-dihydroxy-3-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
3530–19–6	C.I. Direct Red 37	22240	1,3-Naphthalenedisulfonic acid, 8-[[4'-[(4-ethoxy phenyl)azo][1,1'-biphenyl]-4-yl]azo]-7-hydroxy-, disodium salt
3567–65–5	C.I. Acid Red 85	22245	1,3-Naphthalenedisulfonic acid, 7-hydroxy-8-[[4'-[[4-[[(4-methylphenyl)sulfonyl]oxy]phenyl] azo][1,1'-biphenyl]-4-yl]azo]-, disodium salt
3626–28–6	C.I. Direct Green 1	30280	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-6-(phenylazo)-, disodium salt
3811–71–0	C.I. Direct Brown 1	30045	Benzoic acid, 5-[[4'-[[2,4-diamino-5-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl] azo]-2-hydroxy-, disodium salt
4335–09–5	C.I. Direct Green 6	30295	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-6-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-3-[(4-nitrophenyl)azo]-, disodium salt
6358–80–1	C.I. Acid Black 94	30336	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[[4'-[[4-hydroxy-2-[(2-methylphenyl) amino]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-6-[(4-sulfophenyl)azo]-, trisodium salt
6360–29–8	C.I. Direct Brown 27	31725	Benzoic acid, 5-[[4'-[[4-[(4-amino-7-sulfo-1-naphthalenyl)azo]-6-sulfo-1-naphthalenyl]azo] [1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, trisodium salt
6360–54–9	C.I. Direct Brown 154	30120	Benzoic acid, 5-[[4'-[[2,6-diamino-3-methyl-5-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl] azo]-2-hydroxy-3-methyl-, disodium salt
8014–91–3	C.I. Direct Brown 74	36300	Benzoic acid, 3,3'-[(3,7-disulfo-1,5-naphthalenediyl)bis[azo(6-hydroxy-3,1-phenylene)azo[6(or7)-sulfo-4,1-naphthalenediyl]azo[1,1'-biphenyl]-4,4'-diylazo]]bis[6-hydroxy-, hexasodium salt
16071–86–6	C.I. Direct Brown 95	30145	Cuprate(2-), [5-[[4'-[[2,6-dihydroxy-3-[(2-hydroxy-5-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl] -4-yl]azo]-2-hydroxybenzoato(4-)]-, disodium

[FR Doc. 96–25650 Filed 10–4–96; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 52

[CA 043–0017a; FRL–5617–4]

Approval and Promulgation of State Implementation Plans; California State Implementation Plan Revision; Kern County Air Pollution Control District; Santa Barbara County Air Pollution Control District; South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on revisions to the California State Implementation Plan (SIP). The revisions concern rules from the Kern County Air Pollution Control District (KCAPCD), the Santa Barbara County Air Pollution Control District (SBCAPCD), and the South Coast Air Quality Management District (SCAQMD). This approval action will incorporate these rules into the Federally approved SIP. The intended effect of approving these rules is to regulate emissions of volatile organic compounds (VOCs) in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). The rules control VOC emissions from organic solvent degreasing operations, petroleum storage tank degassing, and gasoline transfer and dispensing operations. Thus, EPA is finalizing the approval of these rules into the California SIP under provisions of the CAA regarding EPA action on SIP submittals, SIPs for national primary and secondary ambient air quality standards, and plan requirements for nonattainment areas.

DATES: This action is effective on December 6, 1996 unless adverse or critical comments are received by November 6, 1996. If the effective date is delayed, a timely notice will be published in the Federal Register.

ADDRESSES: Copies of the rules and EPA's evaluation report for each rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rules are also available for inspection at the following locations:

Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, S.W., Washington, D.C. 20460.

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812.

Kern County Air Pollution Control District, 2700 ''M'' Street, Suite 290, Bakersfield, CA 93301.

Santa Barbara County Air Pollution Control District, 26 Castilian Drive, B–23, Goleta, CA 93117.

South Coast Air Quality Management District, 21865 E. Copley Drive, Diamond Bar, CA 91765–4182.

FOR FURTHER INFORMATION CONTACT: Mae Wang, Rulemaking Section (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1200.

SUPPLEMENTARY INFORMATION:

Applicability

The rules being approved into the California SIP include: KCAPCD Rule 412.1, Transfer of Gasoline into Vehicle Fuel Tanks; KCAPCD Rule 410.3, Organic Solvent Degreasing Operations; KCAPCD Rule 102, Definitions; SBCAPCD Rule 343, Petroleum Storage Tank Degassing; and SCAQMD Rule 461, Gasoline Transfer and Dispensing.

Background

On March 3, 1978, EPA promulgated a list of ozone nonattainment areas under the provisions of the Clean Air Act, as amended in 1977 (1977 Act or pre-amended Act), that included the San Joaquin Valley Air Basin,[1] the South Central Coast Air Basin and the Los Angeles-South Coast Air Basin Area. 43 FR 8964, 40 CFR 81.305. These areas did not attain the ozone standard by their approved attainment dates.[2] On May 26, 1988, EPA notified the Governor of California, pursuant to section 110(a)(2) of the 1977 Act, that the KCAPCD, SBCAPCD and SCAQMD portions of the California SIP were inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). On November 15, 1990, the Clean Air Act Amendments of 1990 were enacted. Pub. L. 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q. In amended section 182(a)(2)(A) of the CAA, Congress statutorily adopted the requirement that nonattainment areas fix their deficient reasonably available control technology (RACT) rules for ozone and established a deadline of May 15, 1991 for States to submit corrections of those deficiencies.

On May 20, 1991, the San Joaquin Valley Unified Air Pollution Control District was formed. This district has authority over the San Joaquin Valley Air Basin Portion of Kern County. Thus, as of March 20, 1991, the KCAPCD has authority over only the Southeast Desert Air Basin portion of Kern County.

Section 182(a)(2)(A) applies to areas designated as nonattainment prior to enactment of the CAA amendments and classified as marginal or above as of the date of enactment. It requires such areas to adopt and correct RACT rules pursuant to pre-amended section 172(b) as interpreted in EPA's pre-amendment guidance.[3] EPA's SIP-Call used that guidance to indicate the necessary corrections for specific nonattainment areas. The South Central Coast Air Basin is classified as moderate and the Los Angeles-South Coast Air Basin Area is classified as extreme; therefore, these areas were subject to the RACT fix-up requirement and the May 15, 1991 deadline. All of Kern County is classified as serious. However, the Southeast Desert Air Basin portion of Kern County was not a pre-amendment nonattainment area and, therefore, was not designated and classified upon enactment of the amended Act.[4] For this reason, KCAPCD is not subject to the section 182(a)(2)(A) RACT fix-up requirement. The KCAPCD is, however, still subject to the requirements of EPA's SIP-Call because the SIP-Call included all of Kern County. The substantive requirements of the SIP-Call are the same as those of the statutory RACT fix-up requirement.

This document addresses EPA's direct final action for KCAPCD Rule 412.1, Transfer of Gasoline into Vehicle Fuel Tanks; KCAPCD Rule 410.3, Organic Solvent Degreasing Operations; KCAPCD Rule 102, Definitions; SBCAPCD Rule 343, Petroleum Storage

[1] At the time, Kern County was included in the San Joaquin Valley Air Basin and the Southeast Desert Air Basin. The San Joaquin Valley Air Basin was designated as nonattainment and the Southeast Desert Air Basin was designated as unclassified.

[2] The South Central Coast Air Basin and the Los Angeles- South Coast Air Basin Area received extensions of their attainment dates to December 31, 1987. Kern County's attainment date remained December 31, 1982.

[3] Among other things, the pre-amendment guidance consists of those portions of the proposed post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to Appendix D of November 24, 1987 Federal Register Notice'' (Blue Book) (notice of availability was published in the Federal Register on May 25, 1988); and the existing control technique guidelines (CTGs).

[4] The South Central Coast Air Basin, the Los Angeles-South Coast Air Basin Area, and the San Joaquin Valley Air Basin portion of KCAPCD retained their nonattainment designations and were classified by operation of law pursuant to section 107(d) and 181(a) upon the date of enactment of the CAA. The Southeast Desert Air Basin portion of the KCAPCD was designated nonattainment on November 6, 1991. See 56 FR 56694 (November 6, 1991).