issued in September 1991, but still did not support ISV as a contingent remedy if low temperature thermal desorption was not an effective treatment process at this site.

On September 30, 1991 U.S. EPA signed a ROD Amendment which required the following remedial actions: excavation and staging of contaminated soil, sludge and clay with contamination above the cleanup action levels; conducting a full-scale treatability study to demonstrate the effectiveness of low temperature thermal desorption; processing contaminated soil, sludge and clay in a low temperature thermal desorption device; placing treated materials back in the lagoon and covering with clean fill; in-situ vitrification of contaminated soil, sludge and clay if low temperature thermal desorption was found to not be effective in achieving the cleanup standards; air monitoring during the remedial action; and ground water monitoring following the remedial action for a period of 2 years to assess and confirm the efficacy of low temperature thermal desorption. The State of Michigan concurred with the remedy in the ROD Amendment.

ADC began treating contaminated soils and sludges on January 5, 1992 by low temperature thermal desorption. After this treatment, the soils and sludges met Michigan Act 307 cleanup standards for volatiles and semi-volatile compounds. Treated materials or other soils still exceeding Michigan Act 307 cleanup standards for inorganics were removed for disposal at a landfill determined to be adequately protective.

U.S. EPA issued an Explanation of Significant Differences (ESD) on October 2, 1992 which identified three significant differences from the remedial action selected in the September 30, 1991 ROD. The first significant difference was that treated materials would be disposed of off-site in a Subtitle D landfill, rather than placement of treated materials back into the lagoon and covering them. This decision was made after a focused Risk Assessment identified that manganese presented a human health risk and low temperature thermal desorption of sludges/soils would not reduce concentrations of manganese. The second significant difference was an increase in volume estimates of materials to be remediated from 3,000 cubic yards to 8,000 cubic yards. The third significant difference was an increase in estimated costs from $1.1 million to $6.0 million due to (1) volume increases, (2) increased analytical costs, (3) high soil moistures, and (4) off-site disposal.

On May 9, 1994 U.S. EPA accepted and approved ADC's Final Remedial Action Report for ADC's completion of all site cleanup activities.

Community relations activities for the Site included public meetings, public availability sessions, as well as routine publication of progress fact sheets.

All the completion requirements for this site have been met as specified in OSWER Directive 9320.2–3A. Confirmatory sampling has verified that the September 1990 Record of Decision, and the September 1991 ROD Amendment cleanup objectives have been achieved, and all cleanup objectives specified in the ROD and ROD Amendment have been implemented at the Site.

U.S. EPA, with concurrence of the State of Michigan, has determined that all appropriate responses under CERCLA at the Anderson Development Company Superfund Site have been completed, and that no further cleanup of this Site by responsible parties is necessary. Therefore, U.S. EPA proposes to delete the Site from the NPL.

Dated: August 9, 1995.

**Valdas V. Adamkus,**

*Regional Administrator, U.S. EPA, Region V.*

[FR Doc. 95–21410 Filed 8–29–95; 8:45 am]

BILLING CODE 6560–50–P

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## 40 CFR Part 721

**[OPPTS–50617; FRL–4762–4]**

**RIN 2070–AC37**

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

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) which would require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of benzidine-based chemical substances, defined herein, for any use other than those listed in the regulatory text of this proposed 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 proposed rule may result in significant human exposure. The required notice would provide EPA with the opportunity to evaluate the intended new use and associated activities, before the benzidine-based chemical substances can be introduced into the marketplace, and an opportunity to protect against potentially adverse exposure before it can occur.

**DATES:** Written comments, in triplicate, must be received by September 29, 1995.

**ADDRESSES:** All comments must be sent in triplicate to: TSCA Document Receipt Office (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–G99, 401 M St., SW, Washington, DC 20460. Comments that contain information claimed as confidential must be clearly marked confidential business information (CBI). If CBI is claimed, three additional sanitized copies must also be submitted. Nonconfidential versions of comments on this proposed rule will be placed in the rulemaking record and will be available for public inspection. Comments should include the docket control number. The docket control number for this proposed SNUR is OPPTS–50617. Unit XI. of this preamble contains additional information on submitting comments containing CBI.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: ncic@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number OPPTS–50617. No CBI should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit XII. of this preamble.

The discussion of EPA's risk management strategy in Unit V. of this proposed rule is included only to provide context for this SNUR, and comments are not solicited for this unit.

**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:** The final version of this proposed SNUR would require persons to notify EPA at least 90 days before commencing the

manufacture, import, or processing of the benzidine-based chemical substances listed in this proposed rule for any use other than those listed in proposed § 721.1660 of the regulatory text. These excepted uses are: As a reagent to test for hydrogen peroxide in milk, as a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine, as a stain in microscopy, and as a reagent for detecting blood. The required notice would provide EPA with information needed to evaluate this use and associated activities, and an opportunity to protect against potentially adverse exposure to the chemical substances before it can occur.

## 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 to which 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 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 they manufacture, import, or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)).

Persons subject to the final version of this proposed SNUR would 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 section 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. EPA may take regulatory action 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, and 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.

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 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 the SNUR requirements. The EPA policy 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) (U.S.C. 2625(b)). Provisions requiring persons submitting SNUNs to submit certain fees to EPA are discussed in detail in that **Federal Register** document. Interested persons should refer to the CFR and the cited **Federal Register** document for further information.

## III. Summary of This Proposed Rule

The chemical substances that are the subjects of this proposed SNUR are benzidine-based chemical substances, which shall be defined as any chemical substances that are listed in Table 1. of proposed § 721.1660(b) of the regulatory text.

Because the listed benzidine-based chemical substances are currently used only in small amounts in the following manners, any new use would greatly increase exposure to these chemicals. Therefore, EPA is proposing to designate any use of the listed benzidine-based chemical substances as a significant new use, other than the following uses: Use 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, and as a reagent for detecting blood. These are the only uses of benzidine-based chemical substances identified by EPA as ongoing.

This proposed rule would require persons who intend to manufacture, import, or process benzidine or benzidine-based chemical substances listed in this proposed 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 chemicals for any use designated by this SNUR as a significant new use. The required notice would provide EPA with the opportunity to evaluate the intended use, and, if necessary, to prohibit or limit that use before it occurs.

## IV. Background Information on Benzidine-Based Chemical Substances

Based upon information on the carcinogenicity of benzidine and benzidine-based dyes, the Agency is concerned for all the benzidine-based chemical substances listed in this proposed rule. Because the molecule benzidine can only be isolated for commerce or use in the form of salts, the term ''benzidine'' shall refer to the molecule benzidine, CAS No. 92–87–5, as well as 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 epidemiology 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 the International Agency for Research on Cancer (IARC) as a Group 1 carcinogen, chemicals which are known to cause cancer in humans and animals (Ref. 2). Benzidine is also classified by the EPA as a Group A, human carcinogen (IRIS, 1986).

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. 11) is based on studies of tested representative benzidine-based dyes, as well as benzidine. The overwhelming health concern for benzidine and benzidine-based dyes is bladder cancer in humans, generally believed to be caused through any route of exposure. As of June 1974, OSHA has required 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 ''recognized human carcinogen'' with no Threshold Limit Value (TLV) assigned, and has recommended that

''all exposure to benzidine should be kept to an absolute minimum'' (ACGIH 1986).

Twelve benzidine-based dyes have been demonstrated to metabolize to benzidine in one or more of four species (Ref. 5). 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. 16071–8–6), showed dose-related and statistically significant tumor incidence of the liver, skin, and Zymbal gland 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. 6).

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 5). 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, 6, and 7). 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 is 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. 8).

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 individuals. 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 (NIOSH, 1980). The amount of benzidine found in the urine was more than could be accounted for by only benzidine impurities in the dyes.

Based on models from EPA (Chemical Engineering Branch/Office of Pollution Prevention and Toxics) and industry, reasonable exposure estimates have been calculated for those workers who weigh powder dyes. 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. 9).

## V. EPA's Risk Management Strategy for Benzidine-Based and Benzidine Congener-Based Dyes and Pigments

Comments are not solicited for this unit, as it is included only to provide context for this proposed SNUR.

This proposed SNUR is the first step in EPA's risk management strategy for benzidine-based and benzidine congener-based dyes and pigments.

The main objective of EPA's strategy is to reduce the risks associated with the manufacture and use of benzidine-based and benzidine congener-based dyes and pigments. Benzidine and benzidine-based dyes have been phased out of commerce. The SNUR being proposed in this document is intended to prevent the reintroduction of these chemicals into commerce without prior notice to EPA, thus achieving EPA's objective for these substances.

In order to complete the main objective in regards to benzidine congener-based dyes, EPA is conducting a series of dialogues with dye manufacturers, users, and importers, as well as labor unions, environmental groups, and other agencies. EPA is also working with the Organization for Economic Cooperation and Development (OECD) to coordinate efforts internationally in dealing with these chemicals.

EPA will attempt to develop a series of Memoranda of Understanding (MOUs) with dye manufacturers and importers to address the risk from manufacture and use of benzidine congener-based dyes, which include tolidine-based and nonmetallized dianisidine-based dyes. The Agency has developed alternative strategies, in case voluntary agreements cannot be reached. After the conclusion of these efforts, the Agency may address metallized dianisidine-based dyes and benzidine congener-based pigments. The MOUs are projected for completion during the next year.

## VI. Objectives and Rationale for the Proposed 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). 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 suspected carcinogens.

The 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, as a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine, as a stain in microscopy, and as a reagent for detecting blood. Therefore, any use of these benzidine-based chemical substances, except for those uses listed above, would increase the volume of the chemicals' production as well as the type, form, magnitude, or duration of exposure, and therefore can be identified as a significant new use (Ref. 10).

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

(1) The Agency would receive notice of any company's intent to manufacture, import, or process benzidine-based chemical substances listed in this proposed rule for the significant new uses identified in this proposed rule, before that activity begins.

(2) The Agency would have 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 identified in this proposed rule.

(3) The Agency would be able to 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.

The benzidine-based chemical substances listed in this proposed rule are not currently subject to any Federal regulations that require notification of the Federal Government of activities that might result in adverse exposures to

these substances and provide a regulatory mechanism that could adequately protect human health or the environment from potentially adverse exposure before it occurs.

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

## VII. Alternatives

Before proposing this SNUR, EPA considered the following alternative regulatory actions for the listed benzidine-based chemical substances.

(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 proposed 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 have several drawbacks. First, EPA would not be able to take immediate follow-up regulatory action under TSCA section 5(e) or 5(f) to prohibit or limit the activity. In addition, EPA may not receive important information from small businesses, because such firms are exempt from section 8(a) reporting requirements. In view of the level of health concern 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 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 proposed rule, EPA decided that a SNUR was more appropriate than a section 6 rule because there are currently no ongoing uses of concern to justify a section 6 ban. EPA's concerns are for potential future uses, and the notification which would be required by this proposed SNUR, when final, would be sufficient to allow the Agency make the decisions necessary to protect against such uses.

## VIII. Applicability of Proposed Rule to Uses Occurring Before Effective Date of the 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 the SNUR rather than as of the effective date of the 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 was no longer new.

Persons who begin commercial manufacture, importation, or processing of the listed benzidine-based chemical substances for any significant new use listed in this proposed rule between proposal and the effective date of the SNUR must cease that activity before the effective date of the 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 begin commercial manufacture, importation, or processing of the chemical substances between proposal and the effective date of the SNUR meet the conditions of advance compliance as codified at § 721.45(h), those persons will be considered to have met the requirements of the final SNUR for those activities.

## 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 SNUN. 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.

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 conduct tests 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 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 selecting a protocol for testing the 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. 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 benzidine-based chemical substances listed in this proposed rule. While there is no precise way to calculate the total annual cost of compliance with this proposed 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 proposed rule (OPPTS–50617).

## XI. Comments Containing Confidential Business Information

All comments will be placed in the public record unless the commenter claims that they contain CBI, and the comments are clearly labeled as containing claimed CBI when they are submitted. Because of the need to expedite this process, CBI claims should be accompanied by comments substantiating the claim, as described in

40 CFR 2.204(e)(4). While a part of the record, CBI comments will be treated in accordance with 40 CFR part 2. A sanitized version of all CBI comments should be submitted to EPA, in triplicate, for the public file.

It is the responsibility of the commenter to comply with 40 CFR part 2 so that all materials claimed as confidential may be properly protected. This includes, but is not limited to, clearly indicating on the face of the comment (as well as on any associated correspondence) that information claimed to be CBI is included, or marking ''Confidential,'' ''TSCA CBI,'' or similar designation on the face of each document or attachment in the comment which contains the claimed CBI. Comments not claimed as confidential at the time of submission or not clearly labeled as containing CBI will be placed in the public file. EPA will consider the failure to clearly identify the claimed confidential status on the face of the comment as a waiver of any such claim and will make such information available to the public without further notice to the commenter or business.

## XII. Rulemaking Record

A record has been established for this rulemaking under docket number OPPTS–50617 (including comments and data submitted electronically as described below). The record includes basic information considered by the Agency in developing the proposed rule.

A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Nonconfidential Information Center, Rm. NE–B607, 401 M St., SW., Washington, DC 20460.

Electronic comments can be sent directly to EPA at:
ncic@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

EPA will accept additional materials for inclusion in the record at any time between this proposal and designation of the complete record. EPA will identify the complete rulemaking record by the date of promulgation of the final rule. A public version of this record containing nonconfidential materials 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. E–G099, 401 M St., SW., Washington, DC.

## XIII. 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 Black 38 and Direct Brown 95 dyes.'' NCI Carcinogenesis. Technical Report Series Number 108. 127p (1978).

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

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

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

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

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

(10) USEPA. Regulatory Impact Branch, USEPA/OPPT,EETD, June 1, 1993. ''Production, Uses, and Imports of Benzidine and Benzidine Based Chemicals.'' Prepared by Meridian Research, Inc.

(11) USEPA. Chemical Screening and Risk Assessment Division. ''Benzidine/ Benzidine Congener Dyes Support Document, October 24, 1994.

## XIV. Regulatory Assessment Requirements

### *A. Executive Order 12866*

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a ''significant regulatory action'' as an action likely to result in a rule:

(1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant'').

(2) Creating serious inconsistency or otherwise interfering with an action taken or planned by another agency.

(3) Materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of the recipient thereof.

(4) Raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this order.

Pursuant to the terms of this Executive Order, it has been determined that this proposed 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 is required to consider whether a regulatory action will have an impact on small entities. If the Administrator certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities, then the RFA does not require the EPA to prepare an initial regulatory flexibility analysis (5 U.S.C. 605(b)). Under EPA policy, however, when a proposed rule would have any adverse economic impact on any number of small entities, then EPA will conduct an initial regulatory flexibility analysis that contains an appropriate level of detail. (Habicht, memorandum: Revised Guidelines for Implementing the Regulatory Flexibility Act, EPA, Office of the Administrator, April 9, 1992). EPA has determined that this proposed rule would not have a significant impact on small businesses, but it may have some, minimal, impact in the future.

Consequently, EPA has analyzed the impact of the proposed rule on small entities based upon the criteria in the

Regulatory Flexibility Act. In the SUMMARY unit of this preamble, EPA describes reasons why it is considering taking the proposed action and the objectives of, and legal basis for, the proposed SNUR. This SNUR would apply to any small or large business that may wish to engage in the significant new use described in the proposed rule. It appears that no small or large businesses are currently engaged in activity that is the subject of this proposed 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 proposed SNUR. As of September 1992, the Agency had received no SNUNs in response to any SNURs promulgated by EPA in the past. Unit XIV.C. and the Economic Analysis to support this SNUR (docket number OPPTS–50617) describe the reporting and other requirements of this proposed rule and the costs of compliance. There are no existing Federal rules that may duplicate, overlap, or conflict with this proposal. Finally there are no significant alternatives to this proposed 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.

*C. Unfunded Mandate Reform Act*

EPA has determined that this proposed 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. Thus this proposed rule is not subject to the requirements of sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

*D. Paperwork Reduction Act*

OMB has approved the information collection requirements contained in this proposed rule under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and has assigned OMB control number 2070–0038. 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.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch (2131), U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' The final rule will respond to any OMB or public comments on the information requirements contained in this proposal.

**List of Subjects in 40 CFR Part 721**

Environmental protection, Chemicals, Hazardous materials, Reporting and rcordkeeping requirements, Significant new uses.

Dated: August 23, 1995.

**Charles M. Auer,**

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

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

## PART 721—[AMENDED]

1. The authority citation for part 721 would continue to read as follows:

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

2. 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) Benzidine-based chemical substances, which shall be defined as any chemical substances that are listed in Table 1. under paragraph (b) 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, as a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine, as a stain in microscopy, and as a reagent for detecting blood.

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

TABLE 1.—BENZIDINE-BASED CHEMICAL SUBSTANCES

| Chemical name | C.I. Number | CAS Number |
|---|---|---|
| Acid Red 85 | 22245 | 3567–65–5 |
| Benzidine | n/a | 92–87–5 |
| Benzidine·$Ni^{2+}$ | n/a | 67632–50–2 |
| Benzidine·HCL | n/a | 75752–15–7 |
| Benzidine·2HCL | n/a | 531–85–1 |
| Benzidine·2HF | n/a | 41766–73–8 |
| Benzidine·2HI | n/a | 75534–79–1 |
| Benzidine·HDAC | n/a | 52754–64–0 |
| C.I. Acid Black 66 | 30275 | 6360–59–4 |
| C.I. Acid Black 69 | 30260 | 6486–53–9 |
| C.I. Acid Black 70 | 30355 | 8005–88–7 |
| C.I. Acid Black 94 | 30336 | 6358–80–1 |
| C.I. Acid Red 323 | 22238 | 6358–34–5 |
| C.I. Brown 165 | 22045 | 6486–32–4 |
| C.I. Direct Black 11 | 30240 | 6486–52–8 |
| C.I. Direct Black 14 | 30345 | 4656–30–8 |
| C.I. Direct Black 15 | 22620 | 6426–75–1 |
| C.I. Direct Black 27 | 31810 | 6360–39–0 |
| C.I. Direct Black 29 | 22580 | 3626–23–1 |
| C.I. Direct Black 34 | 35075 | 6473–08–1 |
| C.I. Direct Black 40 | 31760 | 6449–81–6 |
| C.I. Direct Black 41 | 30260 | 6486–53–9 |
| C.I. Direct Black 83 | 31850 | 6837–80–5 |
| C.I. Direct Black 100 | 35415 | 6358–73–2 |
| C.I. Direct Black 131 | 30270 | 6486–54–0 |
| C.I. Direct Blue 11 | 30350 | 6451–04–3 |
| C.I. Direct Blue 16 | 22475 | 6426–66–0 |
| C.I. Direct Blue 19 | 22485 | 6426–68–2 |
| C.I. Direct Blue 38 | 30090 | 1324–83–0 |
| C.I. Direct Blue 42 | 22505 | 6426–71–7 |
| C.I. Direct Blue 43 | 30205 | 7273–59–8 |
| C.I. Direct Blue 48 | 22565 | 6459–89–8 |
| C.I. Direct Blue 49 | 22540 | 6426–73–9 |
| C.I. Direct Blue 51 | 30340 | 6360–65–2 |
| C.I. Direct Blue 58 | 22490 | 6426–69–3 |
| C.I. Direct Blue 64 | 22595 | 6426–74–0 |
| C.I. Direct Blue 131 | 35085 | 6661–39–8 |
| C.I. Direct Blue 177 | 22625 | 6426–76–2 |
| C.I. Direct Blue 230 | 22455 | 6527–65–7 |
| C.I. Direct Brown 5 | 30135 | 6844–77–5 |
| C.I. Direct Brown 7 | 30035 | 6837–86–1 |
| C.I. Direct Brown 13 | 35710 | 8003–82–5 |
| C.I. Direct Brown 14 | 35715 | 8002–97–9 |
| C.I. Direct Brown 17 | 30100 | 6661–48–9 |
| C.I. Direct Brown 20 | 30060 | 1324–67–0 |
| C.I. Direct Brown 21 | 30155 | 6442–05–3 |
| C.I. Direct Brown 24 | 31700 | 8003–74–5 |
| C.I. Direct Brown 25 | 36030 | 33363–87–0 |
| C.I. Direct Brown 26 | 31730 | 8003–55–2 |
| C.I. Direct Brown 27 | 31725 | 6360–29–8 |
| C.I. Direct Brown 33 | 35520 | 1324–87–4 |
| C.I. Direct Brown 39 | 35060 | 6473–06–9 |
| C.I. Direct Brown 43 | 35700 | 6471–44–9 |
| C.I. Direct Brown 46 | 31785 | 8003–51–8 |
| C.I. Direct Brown 51 | 31710 | 4623–91–0 |
| C.I. Direct Brown 54 | 31735 | 8003–50–7 |
| C.I. Direct Brown 56 | 22040 | 6486–31–3 |
| C.I. Direct Brown 57 | 31705 | 6360–28–7 |
| C.I. Direct Brown 58 | 22340 | 6426–59–1 |
| C.I. Direct Brown 60 | 22325 | 6426–57–9 |
| C.I. Direct Brown 61 | 30055 | 6505–33–5 |
| C.I. Direct Brown 62 | 31720 | 8003–56–3 |
| C.I. Direct Brown 68 | 30125 | 6449–85–0 |
| C.I. Direct Brown 70 | 35530 | 6428–42–8 |
| C.I. Direct Brown 73 | 35535 | 6428–43–9 |
| C.I. Direct Brown 75 | 30325 | 1324–84–1 |
| C.I. Direct Brown 79 | 30050 | 6483–77–8 |
| C.I. Direct Brown 86 | 22030 | 6486–30–0 |
| C.I. Direct Brown 101 | 31740 | 8626–29–7 |
| C.I. Direct Brown 138 | 30070 | 6449–84–9 |
| C.I. Direct Brown 151 | 31685 | 10130–38–8 |
| C.I. Direct Brown 159 | 31755 | 10214–11–6 |
| C.I. Direct Brown 171 | 30040 | Unknown |
| C.I. Direct Brown 173 | 30165 | 6826–64–8 |
| C.I. Direct Brown 175 | 30150 | 6528–58–1 |
| C.I. Direct Brown 190 | 31750 | Unknown |
| C.I. Direct Brown 215 | 35720 | 83606–72–8 |
| C.I. Direct Green 7 | 30330 | 6360–64–1 |
| C.I. Direct Green 8 | 30315 | 5422–17–3 |
| C.I. Direct Green 9 | 30310 | 6360–62–9 |
| C.I. Direct Green 10 | 30285 | 6360–61–8 |
| C.I. Direct Green 12 | 30290 | 6486–55–1 |
| C.I. Direct Green 19 | 30305 | 6486–58–4 |
| C.I. Direct Green 21 | 31790 | 8003–52–9 |
| C.I. Direct Green 22 | 31775 | 6860–33–4 |
| C.I. Direct Green 39 | 30220 | 6360–57–2 |
| C.I. Direct Green 58 | 30225 | 110735–26–7 |
| C.I. Direct Green 60 | 22315 | 6426–56–8 |
| C.I. Direct Orange 25 | 22135 | 6486–43–7 |
| C.I. Direct Orange 2 | 22380 | 8005–97–8 |
| C.I. Direct Orange 33 | 22385 | 13190–99–3 |
| C.I. Direct Orange 43 | 22193 | Unknown |
| C.I. Direct Orange 102 | 22190 | 6528–39–8 |
| C.I. Direct Red 10 | 22145 | 2427–70–1 |
| C.I. Direct Red 13 | 22155 | 1937–35–5 |
| C.I. Direct Red 17 | 22150 | 2769–07–5 |
| C.I. Direct Red 18 | 22280 | 6548–26–1 |
| C.I. Direct Red 29 | 22305 | 6426–54–6 |
| C.I. Direct Red 33 | 22306 | 6253–15–2 |
| C.I. Direct Red 42 | 22180 | 6548–39–6 |
| C.I. Direct Red 43 | 22205 | 6486–50–6 |
| C.I. Direct Red 44 | 22500 | 2302–97–8 |
| C.I. Direct Red 52 | 22290 | 6797–93–9 |
| C.I. Direct Red 53 | 22405 | 6375–58–2 |
| C.I. Direct Red 59 | 22420 | 6655–94–3 |
| C.I. Direct Red 60 | 22200 | 6486–49–3 |
| C.I. Direct Red 74 | 22170 | 8003–75–6 |
| C.I. Direct Red 84 | 22360 | 6459–86–5 |
| C.I. Direct Violet 3 | 22445 | 6507–83–1 |
| C.I. Direct Violet 4 | 22555 | 6472–95–3 |
| C.I. Direct Violet 12 | 22550 | 2429–75–6 |
| C.I. Direct Violet 17 | 22465 | 6426–65–4 |
| C.I. Direct Violet 27 | 22460 | 6426–64–8 |
| C.I. Direct Violet 36 | 22470 | 6472–94–2 |
| C.I. Direct Violet 38 | 22630 | 6426–77–3 |
| C.I. Direct Violet 42 | 22450 | 6459–88–7 |
| C.I. Direct Violet 43 | 22440 | 6426–63–7 |
| C.I. Direct Violet 45 | 22510 | 6426–72–8 |
| C.I. Direct Violet 85 | 22520 | 6507–84–2 |
| C.I. Direct Violet 88 | 22046 | 6358–33–4 |
| C.I. Direct Yellow 1 | 22250 | 6472–91–9 |
| C.I. Direct Yellow 20 | 22410 | 6426–62–6 |
| C.I. Direct Yellow 24 | 22010 | 6486–29–9 |
| Direct Black 4 | 30245 | 2429–83–6 |
| Direct Black 38 | 30235 | 1937–37–7 |
| Direct Blue 2 | 22590 | 2425–73–4 |
| Direct Blue 6 | 22610 | 2602–46–2 |
| Direct Brown 1 | 30045 | 3811–71–0 |
| Direct Brown 1.2 | 30110 | 2586–58–5 |
| Direct Brown 2 | 22311 | 2429–82–5 |
| Direct Brown 6 | 30140 | 2883–80–3 |
| Direct Brown 31 | 35660 | 2429–81–4 |
| Direct Brown 59 | 22345 | 3476–90–2 |
| Direct Brown 74 | 36300 | 8014–71–3 |
| Direct Brown 95 | 30145 | 16071–86–6 |
| Direct Brown 154 | 30120 | 6360–54–9 |
| Direct Green 1 | 30280 | 3626–28–6 |
| Direct Green 6 | 30295 | 4335–09–5 |
| Direct Green 8 | 30315 | 5422–17–3 |
| Direct Orange 1 | Mixture | 54579–28–1 |
| | 22370 | 6459–87–6 |
| | 22375 | 13164–93–7 |
| | 22430 | 6472–93–1 |
| Direct Orange 8 | 22130 | 2429–79–0 |
| Direct Red 1 | 22310 | 2429–84–7 |
| Direct Red 28 | 22120 | 573–58–0 |
| Direct Red 37 | 22240 | 3530–19–6 |
| Direct Violet 1 | 22570 | 2586–60–9 |
| Direct Violet 22 | 22480 | 6426–67–1 |

[FR Doc. 95–21518 Filed 8–29–95; 8:45 am]

BILLING CODE 6560–50–F