

petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

II. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. Filing of Objections

Any person who will be adversely affected by this regulation may at any time on or before October 22, 1992, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.
Therefore, under the Federal Food, Drug, and Cosmetic Act and under

authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 178.1010 is amended by adding new paragraphs (b)(41) and (c)(36) to read as follows:

§ 178.1010 Sanitizing solutions.

* * * * *

(b) * * *

(41) An aqueous solution containing *n*-alkyl(C₁₂-C₁₆)benzyltrimethylammonium chloride, having average molecular weights ranging from 351 to 380 wherein the alkyl groups contain principally 12 to 16 carbons and not more than 1 percent each of the groups with 8 and 10 carbon atoms; ammonium chloride (CAS Reg. No. 12125-02-9); calcium stearate (CAS Reg. No. 1529-23-0); sodium bicarbonate (CAS Reg. No. 144-55-9); starch or dextrin, or both starch and dextrin (CAS Reg. No. 9004-53-9); and the optional ingredient methylene blue (CAS Reg. No. 61-73-4). In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(c) * * *

(36) Solutions identified in paragraph (b)(41) of this section shall provide, when ready for use, not less than 150 parts per million and not more than 200 parts per million of *n*-alkyl(C₁₂-C₁₆)benzyltrimethylammonium chloride; and not more than 0.4 part per million of the colorant methylene blue. Components shall be present in the product used to prepare the solution in the following proportions: 1 part *n*-alkyl(C₁₂-C₁₆)benzyltrimethylammonium chloride to 0.24 part ammonium chloride to 0.08 part calcium stearate to 0.60 part sodium bicarbonate to 0.08 part starch or dextrin, or a combination of starch and dextrin.

* * * * *

Dated: September 10, 1992.

Douglas L. Archer,
Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-22950 Filed 9-21-92; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1310 and 1313

Records, Reports, and Exports of Listed Chemicals

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations implementing the Chemical Diversion and Trafficking Act of 1988 (CDTA) by including hydrochloric acid and sulfuric acid as listed essential chemicals for the purpose of imposing controls on exports to cocaine producing areas. The inclusion of these chemicals into the CDTA requires any exporter of these chemicals to targeted countries to comply with the regulated export transaction requirements specified in 21 CFR parts 1310 and 1313.

EFFECTIVE DATE: October 22, 1992.

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

SUPPLEMENTARY INFORMATION:

Introduction

On December 11, 1991, a notice of proposed rulemaking was published by the Administrator of the Drug Enforcement Administration (DEA) in the *Federal Register* (56 FR 64582-64584) to include hydrochloric acid and sulfuric acid as listed essential chemicals under the Chemical Diversion and Trafficking Act (CDTA) of 1988. The proposed rule provided the opportunity for interested parties to submit comments on or before January 10, 1992.

Two interested parties filed comments. A section by section analysis of the comments and the DEA's consideration of them are set forth below.

Substances Covered (1310.02)

One respondent suggested that the proposal, as written, did not clearly specify the forms of the acids to be regulated. It is the intent of the DEA to regulate both concentrated and diluted solutions of hydrochloric acid and sulfuric acid and anhydrous hydrochloric acid, also known as hydrogen chloride gas. The DEA does not consider aqueous solutions of regulated chemicals, including hydrochloric acid and sulfuric acid, to

be mixtures as defined under 21 U.S.C. 802(40).

Another respondent presented the viewpoint that the proposed regulation of hydrochloric acid and sulfuric acid would unfairly discriminate against U.S. exporters since other countries have not, as yet, imposed export controls on these acids to targeted areas. This proposed regulation is in agreement with the recommendations of the Chemical Action Task Force (CATF) which were endorsed by the G-7 nations and the Commission of the European Communities. In addition, hydrochloric and sulfuric acids were proposed for inclusion under Article 12 of the 1988 Vienna Convention. The Commission on Narcotic Drugs (CND), at its thirty-fifth session on April 9, 1992, voted to place sulfuric acid (excluding its salts) and hydrochloric acid (excluding its salts) into Table II of the 1988 Convention. Control under Article 12 requires all parties to the 1988 Convention to apply export control measures to hydrochloric and sulfuric acids.

Maintenance of Records (1310.04)

One respondent requested a clarification of the basis on which the acid threshold quantities were to be calculated. The reason for this comment was the proposal, as written, did not specify the acid forms to be regulated. Since the DEA is regulating all aqueous concentrations of the two acids, the threshold limit parameters for aqueous forms were revised and are based solely on volume measurements. The threshold limit for anhydrous hydrochloric acid, which was omitted from the December 11, 1991 proposal, is based solely on a weight measurement.

One respondent stated that thresholds should be increased to recognize the legitimate high volume use of both acids by the regulated community. The DEA agrees with this comment and has increased the thresholds for both acids.

This rule is necessary to comply with treaty obligations of the United States, and therefore, the countries to which export restrictions apply have been minimized. While exports to listed countries are regulated transactions requiring full application of the controls of the CDTA and its regulations, it is recognized that traffickers may attempt to place orders through third party countries to subsequently be diverted to illegal activities in listed countries. Persons exporting these chemicals should be aware of this potential and exercise due diligence to guard against becoming a party to manipulation. Even though the exports to unlisted countries are not regulated transactions, criminal penalties exist for knowingly and

intentionally distributing or exporting so as to evade the provisions of the CDTA.

The Administrator hereby certifies that this action will have no significant impact on entities whose interests must be considered under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). This amendment to the list of essential chemicals is limited to exports to specified Latin American countries. Most exports of this nature are handled by major chemical manufacturers and distributors who are not small entities as defined in 5 U.S.C. 601(6).

This is not a major rule for purposes of Executive Order (E.O.) 12291. Pursuant to E.O. 12291, this final rule has been submitted for review by the Office of Management and Budget (OMB). The Administrator certifies that these amendments to the DEA's chemical diversion regulations meet the applicable standards set forth in sections 2(a) and 2(b)(2) of E.O. 12778. These regulations, implementing the Chemical Diversion and Trafficking Act, are essential to a criminal law enforcement function of the United States.

This action has been analyzed in accordance with the principles and criteria contained in E.O. 12612, and it has been determined that this rule has no implications which would warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1310

Drug traffic control, Reporting and record keeping requirements.

For reasons set out above, 21 CFR, part 1310, is amended as follows:

PART 1310—[AMENDED]

1. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b).

2. Section 1310.02 is amended by adding paragraphs (b)(8) and (b)(9) to read as follows:

§ 1310.02 Substances covered.

- * * * * *
- (b) * * *
- (8) Hydrochloric acid
- (9) Sulfuric acid
- * * * * *

3. Section 1310.04 is amended by adding paragraph (f)(2)(iv) to read as follows:

§ 1310.04 Maintenance of records.

- * * * * *
- (f) * * *
- (2) * * *
- (iv) Exports to Designated Countries

Chemical	Threshold by volume	Threshold by weight
(A) Hydrochloric acid.	50 gallons.....	27 kilograms.
(7) Anhydrous hydrochloric acid.	
(B) Sulfuric acid.	50 gallons.....	

4. A new § 1310.08 is added to read as follows:

§ 1310.08 Excluded transactions.

Pursuant to 21 U.S.C. 802(39)(A)(iii), regulation of the following transactions has been determined to be unnecessary for the enforcement of the Chemical Diversion and Trafficking Act and, therefore, they have been excluded from the definitions of regulated transactions contained in 21 CFR 1310.01(f) and 1313.02(d):

- (a) Domestic and import transactions of hydrochloric and sulfuric acids.
- (b) Export transactions of hydrochloric and sulfuric acids, except for exports to the following countries:

- (1) Argentina
- (2) Bolivia
- (3) Brazil
- (4) Chile
- (5) Colombia
- (6) Ecuador
- (7) French Guiana
- (8) Guyana
- (9) Panama
- (10) Paraguay
- (11) Peru
- (12) Surinam
- (13) Uruguay
- (14) Venezuela

Dated: June 30, 1992.

Robert C. Bonner,
Administrator of Drug Enforcement.
 [FR Doc. 92-22933 Filed 9-21-92; 8:45 am]
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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR PART 165

[COTP Paducah, KY, Regulation 92-23]

Safety Zone Regulations: Cumberland River, Mile 0.0 to 10.0 and From Mile 24.0 to 30.6

AGENCY: Coast Guard, DOT.
ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone on the Cumberland River from mile 0.0 to 10.0 and from mile 24.0 to 30.6. The safety