

September 17, 2001.

Dichloralphenazone to be surrendered to DEA must be listed on a DEA Form 41, "Inventory of Controlled Substances Surrendered for Destruction." DEA Form 41 and instructions can be obtained from the nearest DEA office.

3. *Security.* Dichloralphenazone must be manufactured, distributed and stored in accordance with 21 CFR 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c) and 1301.76 after September 17, 2001.

4. *Labeling and packaging.* All commercial containers of dichloralphenazone that are packaged on or after February 12, 2002 must have the appropriate Schedule IV labeling and packaging as required by 21 CFR 1302.03–1302.07. Commercial containers of dichloralphenazone packaged before February 12, 2002 and not meeting the requirements specified in 21 CFR 1302.03–1302.07 may be distributed until May 13, 2002. On and after May 13, 2002 all commercial containers of dichloralphenazone must bear the CIV labels as specified in 21 CFR 1302.03–1302.07.

5. *Inventory.* Registrants possessing dichloralphenazone are required to take inventories pursuant to 21 CFR 1304.03, 1304.04 and 1304.11 after September 17, 2001.

6. *Records.* All registrants must keep records pursuant to 21 CFR 1304.03, 1304.04 and 1304.21–1304.23 after September 17, 2001.

7. *Prescriptions.* All prescriptions for dichloralphenazone or prescriptions for products containing dichloralphenazone or prescriptions for products containing dichloralphenazone are to be issued pursuant to 21 CFR 1306.03–1306.06 and 1306.21–1306.26. All prescriptions for dichloralphenazone or products containing dichloralphenazone issued on or before October 15, 2001, if authorized for refilling, shall, as of that date, be limited to five refills and shall not be refilled after February 12, 2002.

8. *Importation and Exportation.* All importation and exportation of dichloralphenazone shall be in compliance with 21 CFR part 1312 after September 17, 2001.

9. *Criminal Liability.* Any activity with dichloralphenazone not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful on or after August 16, 2001, except as authorized in this rule.

Regulatory Certifications

Regulatory Flexibility Act

The Acting Administrator hereby certifies that this rulemaking has been

drafted in a manner consistent with the principles of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). It will not have a significant economic impact on a substantial number of small business entities. Most handlers of dichloralphenazone or prescription products containing this substance are already registered to handle controlled substances and are subject to the regulatory requirements of the CSA.

Executive Order 12866

The Acting Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 section 1(b). DEA has determined that this is not a significant rulemaking action. Therefore, this action has not been reviewed by the Office of Management and Budget.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Plain Language Instructions

The Drug Enforcement Administration makes every effort to write clearly. If you have suggestions as to how to improve the clarity of this regulation, call or write Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, telephone (202) 307-7297.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA [21 U.S.C. 811(a)], and delegated to the Administrator of the DEA by the Department of Justice regulations (21 CFR 0.100), the Acting Administrator hereby rules that 21 CFR part 1308 be amended as follows:

PART 1308—[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

2. Section 1308.14 is amended by redesignating the existing paragraphs (c)(15) through (c)(49) as (c)(16) through (c)(50) and by adding a new paragraph (c)(15) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *
(15) Dichloralphenazone—2467.

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Dated: August 3, 2001.

William B. Simpkins,

Acting Administrator.

[FR Doc. 01-20579 Filed 8-15-01; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[DEA-156FF]

RIN #1117-AA43

Listed Chemicals; Establishment of Non-Regulated Transactions in Anhydrous Hydrogen Chloride

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule confirmation.

SUMMARY: Effective October 3, 1996, the Comprehensive Methamphetamine

Control Act of 1996 (MCA) had the practical effect of directing the DEA to place domestic controls on anhydrous hydrogen chloride. Previously, exports of the listed chemical hydrochloric acid (including anhydrous hydrogen chloride, referred to in the MCA as hydrochloric gas, which is a form of hydrogen chloride) were already regulated pursuant to 21 CFR 1310. A domestic threshold of zero (0.0 kilograms) for anhydrous hydrogen chloride became effective September 1, 2000, by a Final Rule published on August 2, 2000 (65 FR 47309).

Although the threshold for anhydrous hydrogen chloride is established at 0.0 kilogram, DEA has concluded that certain transactions in anhydrous hydrogen chloride are not sources for diversion. The Final Rule establishing a zero threshold for anhydrous hydrogen chloride also provided exemption, on an interim basis, from the recordkeeping and reporting requirements for: (1) Domestic transactions involving pipeline distributions; and (2) domestic distributions of 12,000 pounds (net weight) or more in a single container. Because these exemptions were not discussed in the Notice of Proposed Rulemaking published on September 30, 1997 (62 FR 51072), DEA requested public comment with respect to the exemption for these two types of transactions involving anhydrous hydrogen chloride. The period for public comment closed on September 1, 2000. Two comments were received supporting these exemptions. This publication finalizes the interim rule without change.

EFFECTIVE DATE: The final rule published at 65 FR 47309 remains effective as of August 2, 2000.

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:

A. What Is Anhydrous Hydrogen Chloride?

Anhydrous hydrogen chloride is the water free form of hydrochloric acid and is a List II chemical under the Controlled Substances Act (CSA). The statutory term "hydrochloric gas" used in the MCA refers to a form of hydrogen chloride more properly called anhydrous hydrogen chloride. Anhydrous hydrogen chloride is hydrogen chloride that is free from water. At ambient temperature and normal atmospheric pressure, anhydrous hydrogen chloride exists as a

gas. Therefore, sometimes anhydrous hydrogen chloride is referred to as hydrogen chloride gas or hydrochloric gas.

When the atmospheric pressure is increased and/or the temperature is decreased, anhydrous hydrogen chloride can change from a gas to a liquid. This is sometimes referred to as refrigerated hydrogen chloride. Refrigerated hydrogen chloride is the same as anhydrous hydrogen chloride although the physical state has been changed from a gas to a liquid.

B. What Is DEA Doing in this Rulemaking?

The DEA is finalizing the interim portion of the Final Rule "Listed Chemicals; Final Establishment of Thresholds for Iodine and Hydrochloric Gas (Anhydrous Hydrogen Chloride)," published on August 2, 2000 (65 FR 47309). That rulemaking provided that there would be a zero threshold for domestic transactions involving anhydrous hydrogen chloride. However, it also provided an exemption, on an interim basis, from the recordkeeping and reporting requirements for transactions of anhydrous hydrogen chloride involving pipeline distributions and distributions of 12,000 pounds (net weight) or more in a single container. That is, two new paragraphs were added to Title 21 Section 1310.08 to exclude these types of transactions from the definition of regulated transactions. Although the exemption for these categories became effective upon publication in the **Federal Register**, the DEA sought public comment on these exemptions.

C. Why Is DEA Exempting These Categories of Transactions

The CSA authorizes DEA, pursuant to 21 U.S.C. 802(39)(A)(iii), to remove certain transactions in listed chemicals from the definition of regulated transaction. DEA has determined that transactions in anhydrous hydrogen chloride in the form of refrigerated liquid and transactions involving the direct transfer of anhydrous hydrogen chloride by pipeline are unlikely sources for diversion and should be removed from the definition of regulated transaction. DEA became aware of these types of transactions by the comments received in response to the **Federal Register** proposal to establish thresholds for iodine and anhydrous hydrogen chloride (62 FR 51072).

To better evaluate this request, DEA collected additional information from the affected industry. DEA learned that rail and truck carriers ship refrigerated

liquid only in large containers. The average payload of a rail car is approximately 135,000 pounds. The capacity for tank trucks is approximately 12,000 to 30,000 pounds. These shipments are in single containers holding the specified weights. Specialized equipment and engineering skills are needed to off-load this commodity. Distributors are aware of their customers and are involved in tracking shipments. The DEA believes that anhydrous hydrogen chloride in this form and in these quantities is not likely to be diverted.

DEA has not identified any shipment of refrigerated anhydrous hydrogen chloride less than the tank truck size of approximately 12,000 pounds. Therefore, domestic distributions of anhydrous hydrogen chloride in single container shipments of 12,000 pounds (net weight) or more will be excluded from the definition of regulated transaction. Transactions that involve multiple containers, each containing less than 12,000 pounds of the chemical are regulated transactions even if the aggregate weight is over 12,000 pounds.

D. Comments Received

The DEA received two comments on the exemption of certain transactions of anhydrous hydrogen chloride. Both favored the exemptions as written. One comment supports the exempt categories because of technological restraints that prevent diversion from these sources. The other comment states that these exemptions are in concert with DEA's desire to control sales of cylinders that are used in illicit methamphetamine production.

The DEA will finalize the interim rule without change to exempt the following categories of transactions involving anhydrous hydrogen chloride: (1) Domestic distribution of anhydrous hydrogen chloride weighing 12,000 pounds (net weight) or more in a single container; and (2) Domestic distribution of anhydrous hydrogen chloride by pipeline. Therefore, the interim rule amending 21 CFR Part 1310, which was published in the **Federal Register** on August 2, 2000, at 65 FR 47309 is adopted as a final rule.

Regulatory Flexibility and Small Business Concerns

This regulation will not have a significant economic impact upon a substantial number of small entities that trade in anhydrous hydrogen chloride. This Final Rule excludes from the definition of "regulated transaction" domestic transactions involving anhydrous hydrogen chloride in bulk quantities of 12,000 pounds (net weight)

or more and domestic distribution made by pipeline.

The Administrator in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities for the following reasons: This Rulemaking removes recordkeeping and reporting requirements for certain transactions in anhydrous hydrogen chloride. This action is being taken in response to industry's request to relieve them of regulatory burdens.

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, Section 1(b), Principles of Regulation. The DEA has determined that this rule is not a "significantly regulatory action" under Executive Order 12866, Section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete in domestic and export markets.

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications

to warrant the preparation of a Federalism Assessment.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Plain Language Instructions

The Drug Enforcement Administration makes every effort to write clearly. If you have suggestions as to how to improve the clarity of this regulation, call or write Patricia M. Good, Chief, Liaison and Policy Section, Drug Enforcement Administration, Office of Diversion Control, Washington, DC 20537, Telephone (202) 307-7297.

Therefore, DEA confirms the final rule with request for comment amending 21 CFR Part 1310, which was published in the **Federal Register** on August 2, 2000, at 65 FR 47309, without change.

Dated: August 3, 2001.

William B. Simpkins,

Acting Administrator.

[FR Doc. 01-20578 Filed 8-15-01; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD09-01-110]

RIN 2115-AA97

Safety Zone; Indian Summer Festival 2001, Milwaukee, Wisconsin

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in Port Washington harbor for the Indian Summer Festival 2001 fireworks display. This safety zone is necessary to protect spectators and vessels from the hazards associated with the storage, preparation, and launching of fireworks. This safety zone is intended to restrict vessel traffic from a portion of the Milwaukee harbor, Milwaukee, Wisconsin.

DATES: This temporary rule is effective from 9:45 p.m. (CST) on September 7, 2001, until 10:15 p.m. (CST) on September 9, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD09-01-110] and are

available for inspection or copying at U.S. Coast Guard Marine Safety Office Milwaukee, 2420 South Lincoln Memorial Drive, Milwaukee, WI 53207 between 7 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

LCDR Timothy Sickler, Port Operations Chief, Marine Safety Office Milwaukee, 2420 South Lincoln Memorial Drive, Milwaukee, WI 53207. The phone number is (414) 747-7155.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The permit application did not allow sufficient time for publication of an NPRM followed by a temporary final rule effective 30 days after publication. Any delay of the effective date of this rule would be contrary to the public interest by exposing the public to the known dangers associated with fireworks displays and the possible loss of life, injury, and damage to property.

Background and Purpose

This safety zone is established to safeguard the public from the hazards associated with launching of fireworks from Harbor Island in the outer Milwaukee Harbor. The size of the zone was determined by using previous experiences with fireworks displays in the Captain of the Port Milwaukee zone and local knowledge about wind, waves, and currents in this particular area.

The safety zone will be in effect on both September 7 and 8, 2001, from 9:45 p.m. until 10:45 p.m. (CST). The safety zone will encompass all waters of Lake Michigan bounded by the following coordinates: from the point of origin at 43° 02.209'N, 087° 53.714'W, southeast to 43° 02.117'N, 087° 53.417'W, south to 43° 01.767'N, 087° 53.417'W, southwest to 43° 01.555'N, 087° 53.772'W, and then north along the shoreline back to the point of origin. This also includes the Harbor Island Lagoon area.

All persons and vessels shall comply with the instructions of the Captain of the Port Milwaukee or his designated on scene patrol personnel. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Milwaukee or his designated on scene representative. The Captain of the Port Milwaukee may be contacted via VHF Channel 16.