

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA-209F]

RIN 1117-AA59

**Schedule of Controlled Substances:
Placement of Dichloralphenazone Into
Schedule IV**

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Acting Administrator of the DEA specifically lists the substance dichloralphenazone, including its salts, isomers, and salts of isomers in Schedule IV of the Controlled Substances Act (CSA, 21 U.S.C. 801 et seq.). As a result of this rule, the regulatory controls and criminal sanctions of Schedule IV will be applicable to the manufacture, distribution, dispensing, importation and exportation of dichloralphenazone and products containing dichloralphenazone.

EFFECTIVE DATE: Effective August 16, 2001.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, (202) 307-7183.

SUPPLEMENTARY INFORMATION:**What Is Dichloralphenazone?**

Dichloralphenazone (also known as dichloralantipyrene) is a compound containing two molecules of chloral hydrate (2,2,2-trichloro-1,1-ethanediol) and one molecule of phenazone (1,2-dihydro-1,5-dimethyl-2-phenyl-3H-pyrazol-3-one); CAS No. 480-30-8. Dichloralphenazone is a sedative typically used in combination with isometheptene mucate and acetaminophen in formulating prescription pharmaceuticals for the relief of tension and vascular headaches. When dichloralphenazone is administered or placed in an aqueous solution (a liquid preparation of any substance dissolved in water) it dissociates to form chloral hydrate and phenazone.

Why Is DEA Issuing This Rulemaking?

Schedule IV controlled substances are listed in 21 CFR 1308.14. Section 1308.14(c) lists 49 depressants, including chloral hydrate, that are

Schedule IV controlled substances. The first sentence of 21 CFR 1308.14(c) states that the category of Schedule IV depressants includes "any material, compound, mixture, or preparation which contains any quantity of" the substances listed in the section. Since dichloralphenazone is a compound containing chloral hydrate, it is likewise a Schedule IV depressant.

Since dichloralphenazone has not been recognized as a compound containing chloral hydrate and confusion has existed with regard to its control status, the DEA published a proposed rule in the **Federal Register** on December 11, 2000 (65 FR 77328) to expressly list dichloralphenazone as a Schedule IV depressant. This proposed rule provided 60 days for comments.

Were There Any Comments Regarding the Proposed Rule?

The DEA received two comments regarding the proposal. The Healthcare Distribution Management Association (formerly the National Wholesale Druggists' Association), whose members operate over 200 distribution centers throughout the U.S., requested an additional 30 days from the date of publication of this final rule to comply with security, inventory, recordkeeping and reporting, and importing and exporting requirements for the handling of dichloralphenazone. They felt that moving dichloralphenazone from an uncontrolled status to a controlled status required system and operational changes that could not be implemented immediately upon publication of this final rule. The DEA has no objection to the additional 30 days and is incorporating this change into this final rule.

Elan Pharmaceuticals, manufacturer of Midrin® (a prescription product containing isometheptene, dichloralphenazone and acetaminophen marketed in the U.S. for over 30 years) commented that federal and state authorities have not regulated dichloralphenazone as a Schedule IV substance, physicians and pharmacists have not treated Midrin® as a controlled drug product and major drug compendiums (*Physician's Desk Reference*, *Merck Index*, *Drug Facts and Comparisons*) have not identified dichloralphenazone or Midrin® as a controlled substance. In addition they noted that the DEA interpretation that Midrin® is a scheduled drug would likely affect prescribing practices and raise DEA registration, labeling, recordkeeping and reporting issues and create confusion among practitioners and patients. Further, Elan poses that there is little evidence that Midrin® or

any other dichloralphenazone product has been misused, abused or diverted. The DEA received a formal request from Elan Pharmaceuticals for an exemption for Midrin® as an exempt non-narcotic prescription product. That request will be evaluated according to 21 CFR 1308.31.

The DEA is aware that dichloralphenazone and products containing this substance have not been identified or treated as controlled substances. The determination that dichloralphenazone is a controlled substance is based, in part, on its status as a compound containing chloral hydrate. In addition, numerous drug abuse emergency room episodes have involved Midrin®. The DEA has made every effort to reduce any confusion on the part of handlers of dichloralphenazone or products containing this substance and chose to expressly list this substance in order to eliminate confusion. The DEA invites any other company to submit a formal request for an exemption from Schedule IV regulation for any dichloralphenazone product. The data submitted under 21 CFR 1308.31 are evaluated to determine if such an exemption is warranted.

What Regulatory Requirements Will Be Applied to Handlers of Dichloralphenazone?

Persons who manufacture, distribute, dispense, import, export, store or engage in research with dichloralphenazone must comply with the following regulatory requirements:

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports dichloralphenazone or engages in research or conducts instructional activities or chemical analysis with respect to this preparation must be registered to conduct such activities in accordance with 21 CFR part 1301. Any person who is currently engaged in any of the above activities must submit an application for registration by September 17, 2001 and may continue their activities until the DEA has approved or denied that application.

2. *Disposal of stocks.* Any person who elects not to obtain a Schedule IV registration or is not entitled to such registration must surrender all quantities of currently held dichloralphenazone in accordance with procedures outlined in 21 CFR 1307.21 on or before September 17, 2001, or may transfer all quantities of currently held dichloralphenazone to a person registered under the CSA and authorized to possess Schedule IV control substances on or before

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.

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(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]

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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