

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA-225F]

Schedules of Controlled Substances: Temporary Placement of 2,5-dimethoxy-4-(n)-propylthiophenethylamine Into Schedule I

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

ACTION: Final rule.

SUMMARY: The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this final rule to temporarily place 2,5-dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7) into Schedule I of the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of the CSA. This final action is based on as finding by the Deputy Administrator of the DEA that the placement of 2C-T-7 in Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. As a result of this rule, the criminal sanctions and regulatory controls of Schedule I substances under the CSA will be applicable to the manufacture, distribution, and possession of 2C-T-7.

EFFECTIVE DATE: September 20, 2002.

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

SUPPLEMENTARY INFORMATION:**Under What Authority Is 2C-T-7 Being Temporarily Scheduled?**

The Comprehensive Crime Control Act of 1984 (Pub. L. 98-473), which was signed into law on October 12, 1984, amended section 201 of the CSA (21 U.S.C. 811) to give the Attorney General the authority to temporarily place a substance into Schedule I of the CSA for one year without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. The Attorney General may extend the temporary scheduling up to 6 months. A substance may be temporarily scheduled under the emergency provisions of the CSA if that substance is not listed in any other schedule under section 202 of the CSA (21 U.S.C. 812) or if there is no exemption or approval in effect under 21 U.S.C. 355 for the substance. The Attorney General has delegated his

authority under 21 U.S.C. 811 to the Administrator of DEA (28 CFR 0.100). The Administrator has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

A notice of intent to temporarily place 2C-T-7 into Schedule I of the CSA was published in the *Federal Register* on July 18, 2002 (67 FR 47343). The Deputy Administrator transmitted notice of his intention to temporarily place 2C-T-7 into Schedule I of the CSA to the Assistant Secretary for Health of the Department of Health and Human Services (DHHS). In response to this notification, the Food and Drug Administration has advised DEA that there are no exemptions or approvals in effect under 21 U.S.C. 355 of the Food, Drug and Cosmetic Act for 2C-T-7 and DHHS has no objection to DEA's intention to temporarily place 2,5-dimethoxy-4-(n)-propylthiophenethylamine into Schedule I of the CSA.

What Factors Were Considered in the Determination To Temporarily Schedule 2,5-dimethoxy-4-(n)-propylthiophenethylamine?

As set forth under 21 U.S.C. 811(h), the Deputy Administrator has considered the available data and the following three factors under the CSA (21 U.S.C. 811(c)) that are required for a determination to temporarily schedule a substance:

4. Its history and current pattern of abuse;
5. Scope, duration and significance of abuse; and
6. What, if any, risk there is to the public health.

Additionally, DEA has considered the three criteria for placing a substance into Schedule I of the CSA (21 U.S.C. 812). The data available and reviewed for 2C-T-7 indicate that it has a high potential for abuse, no currently accepted medical use in treatment in the United States and is not safe for use under medical supervision.

What Is 2,5-dimethoxy-4-(n)-propylthiophenethylamine?

2,5-dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7), a phenethylamine, is structurally related to the Schedule I phenethylamine 4-bromo-2,5-dimethoxyphenethylamine (2CB), and other hallucinogens (e.g., 2,5-dimethoxy-4-methylamphetamine (DOM), and 1-(4-bromo-2,5-dimethoxyphenyl)-2-aminopropane (DOB)) in Schedule I of the CSA. 2C-T-7 has those structural features of phenethylamines which are necessary for stimulant and/or hallucinogenic activity; 2C-T-7 is a sulfur analogue of

2CB. Based on these structural features, 2C-T-7 is likely to have a pharmacological profile similar to 2CB and other Schedule I hallucinogens. The similarity in the effects of 2C-T-7 and 2CB has been supported by Shulgin and Shulgin (Pihkal: A Chemical Love Story; pp. 569-570, 1991) and by "self-reports" on the Internet. Shulgin and Shulgin (1991) reported that at an oral dose of 20 mg or 30 mg, 2C-T-7 produced visual hallucinations. They concluded that in terms of being an acceptable hallucinogen, 2C-T-7 was comparable to 2CB and mescaline. Self-reports on the Internet have described the hallucinations resulting from the self-administration of 2C-T-7 as being very 2CB-like, consisting of persistent multiple images, overlaid patterns, and trails. The subjective effects of 2C-T-7 have also been described as being similar to those of 2CB; mood lifting, sense of well being, emotionality, volatility, increased appreciation of music, and psychedelic ideation.

DEA is not aware of any approved therapeutic use of 2C-T-7 in the United States. The safety of this substance for use in humans has never been demonstrated.

Why Is 2C-T-7 Being Controlled?

The continued trafficking and abuse of 2C-T-7 poses an imminent hazard to public safety. The abuse of stimulant/hallucinogenic substances in popular all night dance parties (raves) and in other venues has been a major problem in Europe since the 1990s. In the past several years, this activity has spread to the United States. The Schedule I controlled substance MDMA and its analogues, collectively known as Ecstasy, are the most popular drugs abused at these raves. Their abuse has been associated with both acute and long-term public health and safety problems. These raves have also become venues for the trafficking and abuse of "new non-controlled" substances in place of or in addition to "Ecstasy." 2C-T-7 is one such substance.

Illicit use of 2C-T-7 was first reported in Germany in 1997. 2C-T-7 was placed under the control of German law on January 20, 1998. In October of 1999, 2C-T-7 tablets were being sold in the Netherlands under the trade name "Blue Mystic". Illicit use of 2C-T-7 was reported in Sweden in January of 2000. Currently 2C-T-7 is controlled under the Swedish law pertaining to goods which are dangerous to the public. French Customs authorities reported seizing tablets in 2001 that contained 10 mg of 2C-T-7.

Abuse of 2C-T-7 in the United States was first reported in 1997; an individual

posted his experience associated with the oral ingestion of 20 mg of 2C-T-7 on the Lycaenum website on the Internet. In the year 2000, the abuse of 2C-T-7 by young adults began to spread in the United States as evidenced by widespread discussion on drug website forums and the sale of the substance from an Internet company. The information being discussed on these websites includes the route of administration, recommended doses, and narratives from individuals describing their experiences and effects after self-administering 2C-T-7.

Self-reported experiences and other information posted on these websites indicate that 2C-T-7 is being abused orally (10–50 mg) or intranasally; the oral route is the most common route of abuse. The powder is being mixed in liquids or placed in gelatin capsules. Information posted on these websites indicates that 2C-T-7 is being taken alone or with other drugs, such as MDMA, ketamine, cannabis, N,N-diisopropyl-5-methoxytryptamine (“Foxy Methoxy”) and N,N-dipropyltryptamine (DPT).

Information gathered by DEA indicates that 2C-T-7 has been purchased in powder form over the Internet and distributed as such. In the United States, capsules containing 2C-T-7 powder also have been encountered. In the Netherlands (“Blue Mystics”) and in Canada (“Red Raspberry”), the bulk powder is being processed into tablets.

State and local law enforcement agencies reported 2C-T-7 exhibits seized in the states of Texas and Wisconsin. In Wisconsin, two unrelated exhibits were submitted to the Wisconsin State Crime Laboratory for analysis; the first exhibit consisted of two clear capsules containing 16 to 18 milligrams of white powder and two paper packets. One packet contained 450 milligrams of tan powder and the other paper packet contained 869 milligrams. The powder in these exhibits was identified as 2C-T-7. These two capsules were sold to an informant as “Twenty-Bird Mescaline.” The second exhibit analyzed by the Wisconsin State Crime Laboratory was shown to be a mixture of 2C-T-7 and N,N-dipropyltryptamine (DPT). 2C-T-7 has also appeared in illicit traffic in Tennessee, Washington, and Oklahoma, as evidenced by the 2C-T-7 related deaths in these states. To date, DEA has not identified a clandestine laboratory synthesizing 2C-T-7.

2C-T-7 shares those structural similarities with 2CB and other phenethylamines (i.e., DOB, and DOM) which makes it likely to produce similar public health risks. Sensory distortion and impaired judgment can lead to

serious consequences for both the user and the general public. 2C-T-7 can have lethal effects when abused alone or in combination with other illicit drugs. To date, three deaths have been associated with the abuse of 2C-T-7. The first death occurred in Oklahoma during April of 2000; a young healthy male overdosed on 2C-T-7 following intranasal administration. The co-abuse of 2C-T-7 with MDMA will pose a significant health risk if 2C-T-7 popularity increases in the same venues as with MDMA. The co-abuse of 2C-T-7 with MDMA has resulted in lethal effects. The other two 2C-T-7 related deaths resulted from the co-abuse of 2C-T-7 with MDMA. They both occurred in April of 2001. One young man died in Tennessee while another man died in the state of Washington.

What Is the Effect of This Final Rule?

While the issuance of this final order, 2C-T-7 becomes subject to regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, dispensing, importing and exporting of a Schedule I controlled substance.

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports 2C-T-7 or who engages in research or conducts instructional activities with respect to 2C-T-7 or who proposes to engage in such activities must submit an application for Schedule I registration in accordance with *part 1301* of Title 21 of the Code of Federal Regulations (CFR) by October 21, 2002.

2. *Security.* 2C-T-7 is subject to Schedule I security requirements and must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(a), (c), and (d), 1301.73, 1301.74, 1301.75(a) and (c) and 1301.76 of the Title 21 of the Code of Federal Regulations.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of 2C-T-7 which are distributed on or after October 21, 2002. Shall comply with requirements of §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* Quotas for 2C-T-7 are established pursuant to *part 1303* of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Every registrant required to keep records and who possesses any quantity of 2C-T-7 is required to keep inventory of all stocks of this substance on hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations. Every registrant who desires registration in Schedule I for 2C-T-7 shall conduct an inventory of

all stocks of 2C-T-7 on or before October 21, 2002.

6. *Records.* All registrants are required to keep records pursuant to §§ 1304.03, 1304.4 and §§ 1304.21–1304.23 of Title 21 of the Code of Federal Regulations.

7. *Reports.* All registrants required to submit reports in accordance with § 1304.31 through § 1304.33 of Title 21 of the Code of Regulations shall do so regarding 2C-T-7.

8. *Order Forms.* All registrants involved in the distribution of 2C-T-7 must comply with the order form requirements of *part 1305* of Title 21 of the Code of Federal Regulations.

9. *Importation and Exportation.* All importation and exportation of 2C-T-7 shall be in compliance with *part 1312* of Title 21 of the Code of Federal Regulations.

10. *Criminal Liability.* Any activity with 2C-T-7 not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act occurring on or after September 20, 2002 is unlawful.

Regulatory Certification

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted 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 on a substantial number of small entities. This action temporarily places 2C-T-7 into Schedule I of the CSA.

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 Federalism

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Unfunded Mandates Reform Act

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 it will not significantly or uniquely affect small

governments. Therefore, no actions were deemed necessary under 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 § 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.

List of Subjects in 21 CFR Part 1308

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

Under the authority vested in the Attorney General by Section 201(h) of the CSA (21 U.S.C. 811(h)), and delegated to the Administrator of the DEA by 28 CFR 0.100, and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby amends 21 CFR Part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

2. Section 1308.11 is amended by adding paragraph (g)(5) to read as follows:

§ 1308.11 Schedule I.

(g) * * *

(5) 2,5-dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7), its optical isomers, salts and salts of isomers—7348.

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Dated: September 6, 2002.

John B. Brown, III,

Deputy Administrator.

[FR Doc. 02-23877 Filed 9-19-02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[UT-001-0045a, UT-001-0046a; FRL-7377-9]

Determination of Attainment for the Carbon Monoxide National Ambient Air Quality Standard for Metropolitan Provo; State of Utah, and Approval of Revisions to the Oxygenated Gasoline Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: This action makes a determination of attainment for the carbon monoxide (CO) National Ambient Air Quality Standard (NAAQS) for the metropolitan Provo CO nonattainment area (hereafter Provo area) which was classified as “moderate”. The Provo area was required by the Clean Air Act Amendments of 1990 to attain the CO NAAQS by December 31, 1995. This determination is based on complete, quality assured ambient air quality monitoring data for the years 1994 and 1995. In addition, on September 27, 2001, the Governor submitted revisions to Utah’s rule R307-301 “Utah and Weber Counties: Oxygenated Gasoline Program”. In this action, EPA is determining that the Provo area attained the CO NAAQS and EPA is approving the revisions to rule R307-301.

DATES: This direct final rule is effective on November 19, 2002, without further notice, unless EPA receives adverse comments by October 21, 2002. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments may be mailed to: Richard R. Long, Director, Air and Radiation Program, Mailcode 8P-AR, United States Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado 80202-2466.

Copies of the documents relevant to this action are available for public inspection during normal business hours at the following offices:

United States Environmental Protection Agency, Region VIII, Air and Radiation Program, 999 18th Street, Suite 300, Denver, Colorado 80202-2466; and, Air and Radiation Docket and Information Center, United States Environmental Protection Agency, Room B-108, 1301 Constitution Avenue (Mail Code 6102T) NW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Tim Russ, Air and Radiation Program, Mailcode 8P-AR, United States Environmental Protection Agency, Region VIII, 999 18th Street, Suite 300, Denver, Colorado 80202-2466, Telephone number: (303) 312-6479.

SUPPLEMENTARY INFORMATION:

Throughout this document wherever “we”, “us”, or “our” are used we mean the Environmental Protection Agency.

I. Determination of Attainment for the CO NAAQS for the Provo Area

In this action, we are determining that the metropolitan Provo CO nonattainment area, as described in 40 CFR 81.345, attained the 8-hour CO NAAQS by December 31, 1995, based on quality assured ambient air monitoring data for the years 1994 and 1995. In addition, ambient air quality data show that the area continued to attain the CO NAAQS from 1995 through 2001 (the most recent year for which complete data are available.) This action is being taken pursuant to sections 179 (c)(1) and 186(b)(2) of the Clean Air Act (CAA). This determination of attainment does not redesignate the Provo area to attainment for the CO NAAQS. The CAA requires that for an area to be redesignated to attainment the five criteria in section 107(d)(3)(E) must first be satisfied and EPA must fully approve a maintenance plan for the area.

(a) Background

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). Under section 107(d)(1)(C) of the CAA, we designated the Provo area as nonattainment for CO because the area had been designated as nonattainment before November 15, 1990. We originally designated the Provo area as nonattainment for CO under the provisions of the 1977 CAA Amendments (see 43 FR 8962, March 3, 1978). This designation was reaffirmed by the 1990 CAA Amendments and the Provo area was classified as “moderate” CO nonattainment area with a design value greater than or equal to 12.7 parts per million (ppm). See 56 FR 56694, November 6, 1991. CO nonattainment areas classified as “moderate” were expected to attain the CO NAAQS as expeditiously as practical, but no later than December 31, 1995. Further information regarding this CO classification and the accompanying requirements are described in section 187 of the CAA and in the “General Preamble for the Implementation of Title I of the Clean Air Act Amendments