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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-1394]

Specific Listing for 1-boc-4-piperidone, a Currently Controlled List I Chemical

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is establishing a specific listing and DEA Chemical Code Number for *tert*-butyl 4-oxopiperidine-1-carboxylate (also known as 1-boc-4-piperidone; and CAS Number: 79099-07-3) and its salts as a list I chemical under the Controlled Substances Act (CSA). Although 1-boc-4-piperidone is not specifically listed as a list I chemical of the CSA with its own unique Chemical Code Number, it has been regulated as a list I chemical in the United States as a carbamate of 4-piperidone, a list I chemical, since May 12, 2023. Therefore, DEA is simply amending the list of list I chemicals in its regulations to separately include 1-boc-4-piperidone.

DATES: Effective date [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

A summary of this rule may be found in the docket for this rulemaking at www.regulations.gov.

SUPPLEMENTARY INFORMATION:

tert-Butyl 4-oxopiperidine-1-carboxylate (also known as 1-boc-4-piperidone) is a chemical that is structurally related to 4-piperidone (also known as piperidin-4-one). 4-Piperidone, including its acetals, its amides, its carbamates, its salts, and salts of its acetals, its amides, and its carbamates, and any combination thereof, whenever the existence of such is

possible, is a list I chemical at 21 CFR 1310.02(a)(38). The chemical structure of 1-boc-4-piperidone defines it as a carbamate of 4-piperidone. Accordingly, under 21 CFR 1310.02(a), 1-boc-4-piperidone, as a carbamate of 4-piperidone, is, and continues to be, a regulated list I chemical.[1]

Legal Authority

The Controlled Substances Act (CSA) gives the Attorney General the authority to specify, by regulation, chemicals as list I chemicals.[2] A "list I chemical" is defined as "a chemical that is used in manufacturing a controlled substance in violation of [the CSA] and is important to the manufacture of the controlled substances."[3] The current list of all list I chemicals is available in 21 CFR 1310.02(a). Pursuant to 28 CFR 0.100(b), the Attorney General has delegated her authority to designate list I chemicals to the Administrator of DEA (Administrator).

In addition**,** the United States is a party to the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988 Convention), Dec. 20, 1988, 1582 U.N.T.S. 95. Under Article 12 of the 1988 Convention, when the United States receives notification that a chemical has been added to Table I or Table II of the 1988 Convention, the United States is required to take measures it deems appropriate to monitor the manufacture and distribution of that chemical within the United States and to prevent its diversion, including measures related to international trade.

Background

In a letter dated June 6, 2024, in accordance with Article 12, paragraph 6, of the 1988 Convention, the Secretariat of the United Nations informed the Permanent Mission of the United States of America to the United Nations (Vienna) that the Commission on Narcotic Drugs (CND)

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[1] *See* Designation of 4-Piperidone as a List I Chemical, 88 FR 21902, 21904 (Apr. 12, 2023) ("As a carbamate of 4-piperidone, 1-boc-4-piperidone is subject to this rulemaking.").
[2] 21 U.S.C. 802(34).; 21 U.S.C. 871(b).; 21 CFR 1310.02(c).
[3] *Id*.; *see also* 21 CFR 1300.02(b).

added the chemical 1-boc-4-piperidone to Table I of the 1988 Convention during its 67th Session on March 19, 2024 (CND Dec/67/7). As discussed above, the United States is a party to the 1988 Convention and has certain obligations pursuant to Article 12. Because 1-boc-4-piperidone is a carbamate of 4-piperidone, it has been regulated as a list I chemical of the CSA since May 12, 2023.[4] Therefore, all regulations and criminal sanctions applicable to list I chemicals have been, and remain, applicable to 1-boc-4-piperidone, and the United States has fulfilled its obligations under the 1988 Convention.

Effect of Action

As discussed above, this rule does not affect the continuing status of 1-boc-4-piperidone as a list I chemical in any way. This action, as an administrative matter, establishes a separate, specific listing for 1-boc-4-piperidone in list I of the CSA and assigns a DEA chemical code number for the substance. This action will allow DEA to effectively monitor regulated transactions of 1-boc-4-piperidone, including the manufacture, distribution, importation, or exportation of 1-boc-4-piperidone, and to provide accurate reporting to the International Narcotics Control Board.

Chemical Mixtures of 1-boc-4-piperidone

Pursuant to the final rule published on April 12, 2023,[5] chemical mixtures containing 1-boc-4-piperidone are not exempt from regulatory requirements at any concentration, unless a manufacturer of 1-boc-4-piperidone submits to DEA an application for exemption of a chemical mixture, DEA accepts the application for filing, and DEA exempts the chemical mixture in accordance with 21 CFR 1310.13.

Because even a small amount of 1-boc-4-piperidone can potentially yield a significant amount of finished controlled substances, DEA believes that the continued regulation of

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[4] *See* Designation of 4-Piperidone as a List I Chemical, 88 FR 21902 (Apr. 12, 2023) (effective date of designation was May 12, 2023).
[5] *Id*.

chemical mixtures containing any concentration of 1-boc-4-piperidone as a list I chemical is necessary to prevent its illicit extraction, isolation, and use. 1-Boc-4-piperidone is already subject to domestic control under list I as a carbamate of 4-piperidone, and DEA's current regulations provide that a chemical mixture containing any concentration of 4-piperidone is a list I chemical. As a technical conforming change in connection with the separate listing of 1-boc-4-piperidone, this rule modifies the "Table of Concentration Limits" in 21 CFR 1310.12(c) to reflect that a chemical mixture containing any concentration of 1-boc-4-piperidone is subject to CSA chemical control provisions, including 21 CFR parts 1309, 1310, 1313, and 1316. No additional requirements are being imposed.

Application Process for Exemption of Chemical Mixtures

DEA has implemented an application process to exempt certain chemical mixtures from the requirements of the CSA and its implementing regulations.[6] Manufacturers may apply for an automatic exemption for those mixtures that do not meet the criteria set forth in 21 CFR 1310.12(d). Pursuant to 21 CFR 1310.13(a), DEA may grant an exemption of a chemical mixture, by publishing a final rule in the *Federal Register*, if DEA determines that: (1) the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance, and (2) the listed chemical or chemicals cannot be readily recovered.

Requirements for Handling List I Chemicals

The listing of 1-boc-4-piperidone as a list I chemical continues to subject handlers (manufacturers, distributors, importers, and exporters) and proposed handlers to all the regulatory controls and administrative, civil, and criminal actions applicable to the manufacture, distribution, importation, and exportation of a list I chemical. Since May 12, 2023, persons handling 1-boc-4-piperidone, including regulated chemical mixtures containing 1-boc-4-

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[6] 21 CFR 1310.13 specifies that this chemical mixture is a chemical mixture consisting of two or more chemical components, at least one of which is a list I or list II chemical. *See also* 21 CFR 1300.02 (defining the term "chemical mixture").

piperidone, have been required to comply with list I chemical regulations, including the following:

1. *Registration*. Any person who handles (manufactures, distributes, imports, or exports), or proposes to engage in such handling, of 1-boc-4-piperidone or a chemical mixture containing 1-boc-4-piperidone, must obtain a registration pursuant to 21 U.S.C. 822, 823, 957, and 958. Regulations describing registration for list I chemical handlers are set forth in 21 CFR part 1309. DEA regulations require separate registrations for manufacturing, distributing, importing, and exporting of 1-boc-4-piperidone.[7] Further, a separate registration is required for each principal place of business at one general physical location where list I chemicals are manufactured, distributed, imported, or exported by a person.[8]

DEA notes that under the CSA, "warehousemen" are not required to register and may lawfully possess list I chemicals, if the possession of those chemicals is in the usual course of business or employment.[9] Under DEA implementing regulations, the warehouse in question must receive the list I chemical from a DEA registrant, and shall only distribute the list I chemical back to the DEA registrant at the registered location from which it was received.[10] A warehouse that distributes list I chemicals to persons other than the registrant, at the registered location from which they were obtained, is conducting distribution activities and is required to register as such.

2. *Records and Reports.* Every DEA registrant must maintain records and submit reports to DEA with respect to 1-boc-4-piperidone pursuant to 21 U.S.C. 830 and in accordance with 21 CFR 1310. Pursuant to 21 CFR 1310.04, a record must be made and maintained for two years after the date of a transaction involving a listed chemical, provided the transaction is a regulated transaction.

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[7] 21 CFR 1309.21.
[8] 21 CFR 1309.23(a); *see also* 21 U.S.C. 822(e)(1) (separate registration requirements pertaining to manufacturing or distributing a list I chemical).
[9] 21 U.S.C. 822(c)(2); 21 U.S.C. 957(b)(1)(B).
[10] *See* 21 CFR 1309.23(b)(1).

Each regulated bulk manufacturer of a listed chemical would be required to submit manufacturing, inventory, and use data on an annual basis.[11] Existing standard industry reports containing the required information would be acceptable, provided the information is separate or readily retrievable from the report.

The CSA and its implementing regulations require that each regulated person report to DEA any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of subchapter I of the CSA. In addition, regulated persons must report the following: any proposed regulated transaction with a person whose description or other identifying characteristics DEA has previously furnished to the regulated person, any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person, and any in-transit loss in which the regulated person is the supplier.[12]

3. *Importation and Exportation*. All importation and exportation of 1-boc-4-piperidone must comply with 21 U.S.C. 957, 958, and 971 and be in accordance with 21 CFR part 1313.

4. *Security*. All applicants and registrants must provide effective controls against theft and diversion of list I chemicals in accordance with 21 CFR 1309.71–1309.73.

5. *Administrative Inspection*. Places, including factories, warehouses, or other establishments and conveyances, where registrants or other regulated persons may lawfully hold, manufacture, distribute, or otherwise dispose of a list I chemical or where records relating to those activities are maintained, are controlled premises as defined in 21 U.S.C. 880(a) and 21 CFR 1316.02(c). The CSA allows for administrative inspections of these controlled premises as provided in 21 CFR part 1316, subpart A.[13]

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[11] 21 CFR 1310.05(d).
[12] 21 USC 830(b);21 CFR 1310.05(a) and (b).
[13] 21 U.S.C. 880.

6. *Liability*. Any activity involving 1-boc-4-piperidone not authorized by, or in violation of, the CSA is unlawful, and would subject the person to administrative, civil, and/or criminal action.

REGULATORY ANALYSES

Administrative Procedure Act

Pursuant to the Administrative Procedure Act at 5 U.S.C. 553(b)(B), DEA finds that good cause exists here to dispense with notice-and-comment rulemaking because it is unnecessary. 1-boc-4-piperidone is currently regulated as a list I chemical as a carbamate of 4-piperidone. The addition of a separate listing for 1-boc-4-piperidone and its DEA chemical code number in the list of list I chemicals in 21 CFR 1310.02(a) makes no substantive difference in the status of this chemical as a list I chemical, but instead is "a minor or merely technical amendment in which the public is not particularly interested."[14] Therefore, DEA finds that publishing a notice of proposed rulemaking and soliciting public comment are unnecessary and good cause exists to dispense with these procedures.

In addition, DEA is concerned that delaying the effective date of this rule potentially could cause confusion regarding the regulatory status of 1-boc-4-piperidone. With 1-boc-4-piperidone currently regulated as a list I chemical, and with no additional requirements being imposed through this action, DEA finds good cause exists to make this rule effective immediately upon publication in accordance with 5 U.S.C. 553(d)(3).

Executive Orders 12866, 13563, 14912, and 14294 (Regulatory Review)

This rule was developed in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 14912. This rule is not a significant regulatory action under section 3(f) of E.O. 12866. 1-boc-4-piperidone is already regulated as a list I chemical in the United States, as a

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[14] *National Nutritional Foods Ass'n v. Kennedy*, 572 F.2d 377, 385 (2d Cir. 1978) (quoting S. Rep. No. 79-752, at 200 (1945)). *See also Utility Solid Waste Activities Group v. E.P.A.*, 236 F.3d 749, 755 (D.C. Cir. 2001) (the "unnecessary" prong applicable in "those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public") (internal quotations and citation omitted).

carbamate of the list I chemical 4-piperidone. In this final rule, DEA is making an administrative change by amending its regulations to separately list 1-boc-4-piperidone as a list I chemical and to assign the DEA chemical code number 8331 to this chemical. A separate listing for 1-boc-4-piperidone will not alter the status of 1-boc-4-piperidone as a list I chemical. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB). DEA scheduling actions are not subject to E.O. 14912, Unleashing Prosperity Through Deregulation.

E.O. 14294, Overcriminalization of Federal Regulations, requires agencies promulgating regulations with criminal regulatory offenses potentially subject to criminal enforcement to explicitly describe the conduct subject to criminal enforcement, the authorizing statutes, and the mens rea standard applicable to each element of those offenses. This final rule does not impose a criminal regulatory penalty and is thus exempt from E.O. 14924 requirements.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)[15] applies to rules that are subject to notice and comment under section 553(b) of the APA or other laws. As noted in the above section regarding the applicability of the APA, DEA determined that there is good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this rule will not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." Therefore, neither a Small Government Agency Plan nor any other action is required under the UMRA.

Paperwork Reduction Act of 1995

The action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.[16] This action will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804(2). However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects 21 CFR Part 1310

Administrative practice and procedure, Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

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[15] 5 U.S.C. 601-612.
[16] 44 U.S.C. 3501-3521.

Accordingly, for the reasons set forth in the preamble, DEA amends 21 CFR part 1310 as follows:

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES; IMPORTATION AND EXPORTATION OF CERTAIN MACHINES

1. The authority citation for 21 CFR part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 827(h), 830, 871(b), 890.

2. In § 1310.02, add paragraph (a)(40) to read as follows:

§ 1310.02 Substances covered.

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(a) * * *

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(40) 1-boc-4-piperidone (tert-butyl 4-oxopiperidine-1-carboxylate) and its salts	8331

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3. In § 1310.04:

a. Redesignate paragraphs (g)(1)(iv) through (xix) as paragraphs (g)(1)(v) through (xx), respectively; and

b. Add new paragraph (g)(1)(iv).

The addition reads as follows:

§ 1310.04 Maintenance of records.

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(g) * * *

(1) * * *

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(iv) 1-boc-4-piperidone (*tert*-butyl 4-oxopiperidine-1-carboxylate) and its salts.

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4. In § 1310.12, amend the table in paragraph (c) by adding in alphabetical order the entry for "1-boc-4-piperidone (*tert*-butyl 4-oxopiperidine-1-carboxylate) and its salts" to read as follows:

§ 1310.12 Exempt chemical mixtures.

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(c) * * *

TABLE OF CONCENTRATION LIMITS

	DEA chemical code number	Concentration	Special conditions
List I Chemicals			
* * * * * * *			
1-boc-4-piperidone (*tert*-butyl 4-oxopiperidine-1-carboxylate) and its salts ……	8331	Not exempt at any concentration	Chemical mixtures containing any amount of 1-boc-4-piperidone (*tert*-butyl 4-oxopiperidine-1-carboxylate) and its salts are not exempt
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SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on September 30, 2025, by Administrator Terrance Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an

official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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