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Issued on November 30, 2023.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-1222]

Specific Listing for Three Currently Controlled Schedule I Substances

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is establishing a specific listing and DEA Controlled Substances Code Number (drug code) for three substances: *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1*H*-indazole-3-carboxamide (also known as ADB-BUTINACA); 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one (also known as α -PiHP or *alpha*-PiHP); and 2-(methylamino)-1-(3-methylphenyl)propan-1-one (also known as 3-MMC or 3-methylmethcathinone) in schedule I of the Controlled Substances Act (CSA). Although ADB-BUTINACA, α -PiHP, and 3-MMC are not specifically listed in schedule I of the CSA with their own unique drug codes, they are schedule I controlled substances in the United States because they are positional isomers of AB-PINACA (controlled January 30, 2015), α -PHP (controlled July 18, 2019), and mephedrone (controlled as a hallucinogen July 9, 2012), respectively, each of which are schedule I hallucinogens. Therefore, DEA is simply amending the schedule I hallucinogenic substances list in its regulations to separately include ADB-BUTINACA, α -PiHP, and 3-MMC.

DATES: Effective December 13, 2023.

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

SUPPLEMENTARY INFORMATION:

ADB-BUTINACA Control

ADB-BUTINACA (also known as *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1*H*-indazole-3-carboxamide) is a chemical substance that is structurally related to AB-PINACA (also known as *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide). AB-PINACA is listed as a hallucinogenic substance in schedule I at 21 CFR 1308.11(d)(70). The introductory text to paragraph (d) provides: (1) A listed substance includes “any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation,” and (2) the term “isomer” includes the “optical, position[al], and geometric isomers.”

When compared to the chemical structure of AB-PINACA, ADB-BUTINACA meets the definition of a positional isomer in 21 CFR 1300.01(b), which cross-references the term “positional isomer” in 21 CFR 1308.11(d). Both AB-PINACA and ADB-BUTINACA possess the same molecular formula and core structure, and they have the same functional groups. They only differ from one another by a rearrangement of an alkyl moiety between functional groups that does not create new chemical functionalities or destroy existing chemical functionalities. Accordingly, under 21 CFR 1308.11(d), ADB-BUTINACA, as a positional isomer of AB-PINACA, has been and continues to be a schedule I controlled substance.¹

α -PiHP Control

α -PiHP (also known as 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one or *alpha*-PiHP) is a chemical substance that is structurally related to α -PHP (also known as 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one). α -PHP is listed as a hallucinogenic substance in schedule I at 21 CFR 1308.11(d)(95). When compared to the chemical structure of α -PHP, α -PiHP meets the definition of a positional isomer in 21 CFR 1300.01(b),

¹ AB-PINACA (and its isomers) has been subject to temporary schedule I controls since January 30, 2015, first pursuant to a final order (January 30, 2015, 80 FR 5042) and the subsequent one-year extension of that order (January 27, 2017, 82 FR 8590), and then permanently pursuant to a final rule, which continued the imposition of those controls (October 16, 2017, 82 FR 47971).

which cross-references the term “positional isomer” in 21 CFR 1308.11(d). Both α -PHP and α -PiHP possess the same molecular formula and core structure, and they have the same functional groups. They only differ from one another by a rearrangement of an alkyl moiety that does not create new chemical functionalities or destroy existing chemical functionalities. Accordingly, under 21 CFR 1308.11(d), α -PiHP, as a positional isomer of α -PHP, has been and continues to be a schedule I controlled substance.²

3-MMC Control

3-MMC (also known 2-(methylamino)-1-(3-methylphenyl)propan-1-one or 3-methylmethcathinone) is a chemical substance that is structurally related to mephedrone (also known as 4-methylmethcathinone). Mephedrone is listed as a hallucinogenic substance in schedule I at 21 CFR 1308.11(d)(36). When compared to the chemical structure of mephedrone, 3-MMC meets the definition of a positional isomer in 21 CFR 1300.01(b), which cross-references the term “positional isomer” in 21 CFR 1308.11(d). Both mephedrone and 3-MMC possess the same molecular formula and core structure, and they have the same functional groups. They only differ from one another by a repositioning of an alkyl moiety. Accordingly, under 21 CFR 1308.11(d), 3-MMC, as a positional isomer of mephedrone, has been and continues to be a schedule I controlled substance.³

The Drug Enforcement Administration’s (DEA) Authority To Control ADB-BUTINACA, α -PiHP, and 3-MMC

This rule is prompted by a letter dated May 17, 2023, in which the United States government was informed by the Secretariat of the United Nations that ADB-BUTINACA, α -PiHP, and 3-MMC have been added to Schedule II of the Convention on Psychotropic Substances of 1971 (1971 Convention). This letter was prompted by decisions at the 66th Session of the Commission on Narcotic Drugs (CND) in March 2023 to schedule ADB-BUTINACA, α -PiHP, and 3-MMC under Schedule II of the 1971

² α -PHP (and its isomers) has been subject to temporary schedule I controls since July 18, 2019, first pursuant to a temporary scheduling order (July 18, 2019, 84 FR 34291) and the subsequent one-year extension of that order (July 16, 2021, 86 FR 37672), and then permanently pursuant to a final rule which continued the imposition of those controls (June 1, 2022, 87 FR 32996).

³ Positional isomers of mephedrone have been subject to permanent schedule I controls since July 9, 2012 (Synthetic Drug Abuse Prevention Act of 2012 or SDAPA, Public Law 112-144, Title XI, Subtitle D).

Convention (CND Decisions 66/5, 66/6, and 66/7). Preceding these decisions, the Food and Drug Administration (FDA), on behalf of the Secretary of Health and Human Services and pursuant to 21 U.S.C. 811(d)(2), published two notices in the **Federal Register** with an opportunity to submit domestic information and opportunity to comment on this action (August 3, 2022, 87 FR 47428 and February 17, 2023, 88 FR 10344). In each instance, FDA noted that ADB-BUTINACA, α -PiHP, and 3-MMC were already controlled in schedule I of the Controlled Substances Act (CSA) as positional isomers of AB-PINACA, α -PHP, and mephedrone, respectively, and the February 2023 notice stated that no additional permanent controls for ADB-BUTINACA, α -PiHP, and 3-MMC under the CSA would be necessary to fulfill United States' obligations as a party to the 1971 Convention.

As discussed above in this final rule, ADB-BUTINACA—by virtue of being a positional isomer of AB-PINACA—has been controlled in schedule I of the CSA temporarily since January 30, 2015 (80 FR 5042), and permanently since October 16, 2017 (82 FR 47971). α -PiHP, a positional isomer of α -PHP, has been controlled in schedule I of the CSA temporarily since July 18, 2019 (84 FR 34291), and permanently since June 1, 2022 (87 FR 32996). 3-MMC, a positional isomer of mephedrone, has been controlled in schedule I of the CSA permanently since July 9, 2012 (Pub. L. 112-144, Title XI, Subtitle D). Therefore, all regulations and criminal sanctions applicable to schedule I substances have been and remain applicable to ADB-BUTINACA, α -PiHP, and 3-MMC. Drugs controlled in schedule I of the CSA satisfy and exceed the required domestic controls of Schedule II under Article 2 of the 1971 Convention.

Effect of Action

As discussed above, this rule does not affect the continuing status of ADB-BUTINACA, α -PiHP, and 3-MMC as schedule I controlled substances in any way. This action, as an administrative matter, merely establishes a separate, specific listing for ADB-BUTINACA, α -PiHP, and 3-MMC in schedule I of the CSA and assigns a DEA controlled substances code number (drug code) for these substances. This action will allow DEA to establish an aggregate production quota and grant individual manufacturing and procurement quotas to DEA-registered manufacturers of ADB-BUTINACA, α -PiHP, or 3-MMC, who had previously been granted individual quotas for such purposes

under the drug codes for AB-PINACA, α -PHP, or mephedrone.

Regulatory Analyses

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest (5 U.S.C. 553). ADB-BUTINACA, α -PiHP, and 3-MMC are currently controlled in schedule I as positional isomers of AB-PINACA, α -PHP, and mephedrone, respectively.

Pursuant to 5 U.S.C. 553(b) (B), DEA finds that notice and comment rulemaking is unnecessary and that good cause exists to dispense with these procedures. The addition of a separate listing for ADB-BUTINACA, α -PiHP, and 3-MMC and their DEA controlled substances code numbers in the list of schedule I substances in 21 CFR 1308.11(d) makes no substantive difference in the status of these drugs as schedule I controlled substances, but instead is “a minor or merely technical amendment in which the public is not particularly interested.” *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 “is confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and public”) (internal quotations and citation omitted). This rule is a “technical amendment” to 21 CFR 1308.11(d) as it is “insignificant in nature and impact, and inconsequential to the industry and public.” Therefore, publishing a notice of proposed rulemaking and soliciting public comment are unnecessary.

In addition, because ADB-BUTINACA, α -PiHP, and 3-MMC are already subject to domestic control under schedule I as positional isomers and no additional requirements are 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). DEA is concerned that delaying the effective date of this rule potentially could cause confusion regarding the regulatory status of ADB-BUTINACA, α -PiHP, and 3-MMC. ADB-BUTINACA, α -PiHP, and 3-MMC are currently controlled as schedule I controlled

substances, and this level of control does not change with this rulemaking.

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 14094 (Modernizing Regulatory Review)

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 14094. This rule is not a significant regulatory action under section 3(f) of E.O. 12866. ADB-BUTINACA, α -PiHP, and 3-MMC are already controlled substances in the United States under schedule I, as they are positional isomers of schedule I hallucinogens AB-PINACA, α -PHP, and mephedrone, respectively. In this final rule, DEA is merely making an administrative change by amending its regulations to separately list ADB-BUTINACA, α -PiHP, and 3-MMC in schedule I and to assign DEA controlled substances code numbers to these substances. A separate listing for ADB-BUTINACA, α -PiHP, and 3-MMC and their DEA controlled substances code numbers will not alter the status of these substances as a schedule I controlled substances. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

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, 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 on 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) (5 U.S.C. 601–612) 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 was good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would 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.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1532, DEA has determined that this action would 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 UMRA of 1995.

Congressional Review Act

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

Signing Authority

This document of the Drug Enforcement Administration was signed on December 7, 2023, by Administrator Anne Milgram. 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**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. Amend § 1308.11 by adding new paragraphs (d)(102) to (104) to read as follows:

§ 1308.11 Schedule I.

* * * * *
(d) * * *

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(102) <i>N</i> -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1 <i>H</i> -indazole-3-carboxamide (other name: ADB–BUTINACA)							7027
(103) 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one (other names: α -PiHP; <i>alpha</i> -PiHP)							7551
(104) 2-(methylamino)-1-(3-methylphenyl)propan-1-one (other names: 3–MMC; 3-methylmethcathinone)							1259
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[FR Doc. 2023–27292 Filed 12–12–23; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0657; FRL–11567–01–OCSPP]

Dodine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of dodine in or on Fruit, pome, group 11–10; Fruit, stone, group 12–12; Nut, tree, group 14–12; and Olive, with pit. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 13, 2023. Objections and requests for hearings must be received on or before February 12, 2024, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0657, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).