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

SUPPLEMENTARY INFORMATION: This final rule designates methyl alpha-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanone) and its optical isomers as a list I chemical. This action subjects handlers of MAPA to the chemical regulatory provisions of the Controlled Substances Act (CSA) and its implementing regulations. This rulemaking does not establish a threshold for domestic and international transactions of MAPA. As such, all MAPA transactions are regulated, regardless of transaction size, and are subject to control under the CSA.

In addition, chemical mixtures containing MAPA are not exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of MAPA are regulated pursuant to the CSA.

Legal Authority
The CSA and the Drug Enforcement Administration’s (DEA) implementing regulations give the Attorney General, as delegated to the Administrator of DEA (Administrator), the authority to specify, by regulation, a chemical as a “list I chemical.” This term refers to a chemical that is used in manufacturing a controlled substance in violation of subchapter I (Control and Enforcement) of the CSA and is important to the manufacture and distribution of that chemical within the United States and to prevent its diversion, including measures related to international trade.

The United States is a Party to the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988 Convention), December 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 May 7, 2020, the Secretary-General of the United Nations, in accordance with Article 12, paragraph 6 of the 1988 Convention, informed the United Nations Secretary of State that the Commission on Narcotic Drugs (CND) voted to place the chemical methyl alpha-phenylacetoacetate (MAPA), including its optical isomers, in Table I of the 1988 Convention (CND Decision 63/1) at its 63rd Session on March 4, 2020. On March 30, 2021, DEA published a notice of proposed rulemaking (NPRM) [86 FR 16558] to designate methyl alpha-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanone) and its optical isomers as a list I chemical under the CSA. In the NPRM, the Acting Administrator found that MAPA is used in, and is important to, the manufacture of the schedule II substances phenylacetone (also known as phenyl-2-propanone, P2P, or benzyl methyl ketone), methamphetamine, and amphetamine. Clandestine laboratory operators have circumvented the schedule II controls on P2P by developing a variety of synthetic methods for producing P2P, which they then convert to methamphetamine and amphetamine.

MAPA is a close chemical relative of precursors controlled under the CSA and the 1988 Convention (e.g., alpha-phenylacetoacetanilide (APAA) and alpha-phenylacetoacetamide (APAA)) and the timing of its emergence suggests it is trafficked to circumvent these precursor controls, particularly the more recent control on APAA. DEA has not identified any known legitimate use for MAPA, other than in small amounts for research, development, and laboratory analytical purposes. The International Narcotics Control Board (INCB) notes that MAPA does not have any legitimate use, and despite this, the INCB highlighted an increase in the frequency of seizures and amounts seized reported through Precursors Incident Communication System (PICS) since November 2018. This trend continued

The CND added APAA and APAA to Table I of the 1988 Convention in March 2014 and March 2019, respectively. DEA designated APAA and APAA as list I chemicals on July 14, 2017 (effective date: August 14, 2017) [82 FR 32457], and May 10, 2021 (effective date: June 9, 2021) [86 FR 24703], respectively, with a correction notice for APAA on June 7, 2021 [86 FR 30169].

Statement by Mr. Cornelis de Joncheere, President, International Narcotics Control Board, Reconstituted sixty-second session of the Commission on Narcotic Drugs, 13 December 2019, at 1.

The Precursors Incident Communication System or PICS is a worldwide, real-time, on-line tool for communication and information sharing between

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
21 CFR Part 1310
[Docket No. DEA–678]

Designation of Methyl alpha-phenylacetoacetate, a Precursor Chemical Used in the Illicit Manufacture of Phenylacetone, Methamphetamine, and Amphetamine, as a List I Chemical

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rulemaking.

SUMMARY: The Drug Enforcement Administration is finalizing, without change, a March 30, 2021, notice of proposed rulemaking to designate the chemical methyl alpha-phenylacetoacetate (also known as MAPA; methyl 3-oxo-2-phenylbutanone; methyl 2-phenylacetate; p-aceetylbenzeneacetic acid, methyl ester; and CAS Number: 16648–44–5) and its optical isomers as a list I chemical under the Controlled Substances Act (CSA). Methyl alpha-phenylacetoacetate is used in clandestine laboratories to illicitly manufacture the schedule II controlled substances phenylacetone (also known as phenyl-2-propanone, P2P, or benzyl methyl ketone), methamphetamine, and amphetamine and is important to the manufacture of these controlled substances. This final rulemaking subjects handlers (manufacturers, distributors, importers, and exporters) of MAPA to the chemical regulatory provisions of the CSA and its implementing regulations.

DATES: Effective December 20, 2021.

* Commissioner Berkovitz submitted his written vote on this matter prior to departing the Commission on October 15, 2021.

* 21 U.S.C. 802(34) and 871(b) and 21 CFR 1310.02(c).

* 21 U.S.C. 802(34) and 21 CFR 1300.02(b).
into 2020, with 37 incidents involving MAPA reported through PICS in the first 10 months of the year, totaling almost 21.5 metric tons.6

As noted in the NPRM, by DEA’s designating MAPA as a list I chemical, the United States will fulfill its obligations under Article 12 of the 1988 Convention. The NPRM requested public comments on the proposed designation; however, DEA did not receive any comments.

Designation of MAPA and Its Optical Isomers as a List I Chemical

For the reasons discussed in the NPRM and reiterated in the above background section, the Administrator finds that MAPA is used in the manufacture of controlled substances in violation of the CSA and is important to the manufacture of these controlled substances. Therefore, the Administrator designates MAPA and its optical isomers as a list I chemical.

Chemical Mixtures of MAPA

Pursuant to this final rulemaking, chemical mixtures containing MAPA are subject to regulatory requirements at any concentration unless a manufacturer 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 (Exemption of chemical mixtures by application). Since even a small amount of MAPA can potentially yield a significant amount of controlled substances, DEA believes that regulation of chemical mixtures containing any amount of MAPA is necessary to prevent its illicit extraction, isolation, and use. This rule modifies the “Table of Concentration Limits” in 21 CFR 1310.12(c) to reflect the fact that a chemical mixture containing any amount of MAPA is subject to CSA chemical control provisions, including recordkeeping and reporting requirements in addition to the CSA registration requirement.

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.7 Manufacturers may submit an application for exemption for those mixtures that do not meet the criteria set forth in 21 CFR 1310.12(d) for an automatic exemption. 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 designation of MAPA as a list I chemical subjects handlers (manufacturers, distributors, importers, and exporters) and proposed handlers to all of the regulatory controls and administrative, civil, and criminal actions applicable to the manufacture, distribution, importation, and exportation of a list I chemical. Upon the effective date of this final rulemaking, persons potentially handling MAPA, including regulated chemical mixtures containing MAPA, are required to comply with the following list I chemical regulations:

1. Registration. Any person who handles (manufactures, distributes, imports, or exports), and engages in such handling of, MAPA or a chemical mixture containing MAPA, must obtain a registration pursuant to 21 U.S.C. 822, 823, 957, and 958.

2. Records and Reports. Every DEA registrant must maintain records and submit reports to DEA with respect to MAPA pursuant to 21 U.S.C. 830(a) and (b)(1) and (2) and in accordance with 21 CFR 1310.04 and 1310.05. 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.

Each regulated bulk manufacturer of a listed chemical must submit to DEA
manufacturing, inventory, and use data on an annual basis. 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 must 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 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.

3. 

Importation and Exportation. All importation and exportation of MAPA must be done in compliance with 21 U.S.C. 957, 958, and 971 and in accordance with 21 CFR part 1313.

4. Security. All applicants and registrants must provide effective controls against theft and diversion 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, must be 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.

6. Liability. Any activity involving MAPA not authorized by, or in violation of, the CSA is unlawful, and may subject the person to administrative, civil, and/or criminal action.

Finalization of Proposed Rule

DEA did not receive any comments on the NPRM proposing to designate the chemical methyl alpha-phenylacetooacetate (also known as MAPA; methyl 3-oxo-2-phenylbutanoate; methyl 2-phenylacetooacetate; \(\alpha\)-acetylbenzeneacetic acid, methyl ester; and CAS Number: 16648-44-3) and its optical isomers as a list I chemical under the CSA. For the reasons discussed in this rulemaking, DEA is finalizing the NPRM without any change.

Regulatory Analyses

Executive Orders 12866 and 13563, Regulatory Planning and Review and Improving Regulation and Regulatory Review

This rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866.

Section 3(f) of E.O. 12866 classifies a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the E.O. As set forth below in the “Costs” discussion, this rule will not be a “significant regulatory action” under E.O. 12866, section 3(f). Since this rule merely designates MAPA and its optical isomers as a list I chemical, DEA believes that this rule does not create or cause the other effects described in section 3(f)(2)-(4). OMB has determined that this rule is not a “significant regulatory action” under E.O. 12866, section 3(f).

As finalized, MAPA is subject to all the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of list I chemicals.

MAPA is a close chemical relative of precursors controlled under the 1988 Convention (e.g., APAAN and APAA), as discussed in the above background section. MAPA is a precursor of methamphetamine and amphetamine, and it is highly suitable for the illicit manufacture of P2P, a precursor listed in Table I of the 1988 Convention. As noted earlier, incidents of illicit manufacture and trafficking of MAPA have been reported to the INCB with an increase in the frequency of seizures and amounts seized since November 2018.

DEA has searched information in the public domain for any legitimate uses of MAPA. Other than the small amounts for research, development, and laboratory analytical purposes, DEA has not documented any industrial use for MAPA except for it being a chemical intermediate in the production of the schedule II substances P2P, methamphetamine, and methamphetamine. Legal conversion of MAPA to P2P in the United States, if it takes place at all, is limited to small, gram quantities. Therefore, DEA concludes the vast majority of, if not all, MAPA is used for the manufacturing of illicit P2P, methamphetamine, and amphetamine.

DEA cannot rule out the possibility that minimal quantities of MAPA are used for the manufacturing of legitimate P2P. However, DEA did not receive any public comments to that effect in response to the NPRM.

DEA evaluated the costs and benefits of this action.

Costs

As stated above, the only use for MAPA of which DEA is aware is as a chemical intermediate for the manufacture of P2P, methamphetamine, and amphetamine. Any manufacturer, distributor, importer, or exporter of MAPA for the production of legitimate P2P, methamphetamine, and amphetamine, if they exist at all, will incur costs if they are not already registered for handling list I chemicals. The primary costs associated with this rule are the annual registration fees for manufacturers ($3,699) and for distributors, importers, and exporters ($1,850). Moreover, any manufacturer that uses MAPA for legitimate P2P, methamphetamine, and amphetamine production would already be registered with DEA and have all security and other handling processes established because of the controls already in place on P2P, methamphetamine, and amphetamine, resulting in minimal cost to those entities.
DEA has identified five domestic suppliers of MAPA, only one of which is registered with DEA to handle list I chemicals. The amount of MAPA distributed by these suppliers is unknown. It is common for chemical distributors to have items on their catalog while not actually having any material level of sales. Based on the discussion above, DEA believes any quantity of sales from these distributors for legitimate pharmaceutical purposes is minimal. As finalized, suppliers for the legitimate use of MAPA are expected to choose the least-cost option, which in many cases may lead them to stop selling the minimal quantities, if any, of MAPA, rather than incur the registration cost. Therefore, DEA estimates that the cost of foregone sales is minimal; and thus, the cost of this rule is minimal.

Benefits

Controlling MAPA is expected to prevent, curtail, and limit the unlawful manufacture and distribution of the controlled substances P2P, methamphetamine, and amphetamine. This action is also expected to assist in preventing the possible theft or diversion of MAPA from any legitimate firms. DEA also believes control is necessary to prevent unscrupulous chemists from synthesizing MAPA and selling it (as an unregulated material) through the internet and other channels, to individuals who may wish to acquire an unregulated chemical intermediate for the purpose of manufacturing illicit P2P, methamphetamine, and amphetamine.

In summary, DEA conducted a quantitative analysis of costs and benefits. DEA believes this action will minimize the diversion of MAPA. DEA believes the legitimate market for MAPA for the legitimate manufacturing of P2P, methamphetamine, and amphetamine is minimal. Thus, any potential cost resulting from this regulation is minimal.

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 Federal 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 (RFA)

The Administrator, in accordance with the RFA, has reviewed this rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

As discussed above, MAPA will now become subject to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, and exportation of list I chemicals. MAPA is used in, and is important to, the illicit manufacture of the schedule II-controlled substances P2P, methamphetamine, and amphetamine. DEA has not identified any legitimate industrial use for MAPA, other than its role as a chemical intermediate in the production of P2P, methamphetamine, and amphetamine. Legal conversion of MAPA to P2P in the United States is limited to small, gram quantities. Legal conversion of any economic impact to those businesses that facilitate the manufacturing and distribution of MAPA for the illicit production of P2P, methamphetamine, and amphetamine.

In summary, DEA conducted a qualitative analysis of costs and benefits. DEA believes this action will minimize the diversion of MAPA. DEA believes the legitimate market for MAPA for the legitimate manufacturing of P2P, methamphetamine, and amphetamine is minimal. Thus, any potential cost resulting from this regulation is minimal.

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In summary, DEA conducted a qualitative analysis of costs and benefits. DEA believes this action will minimize the diversion of MAPA. DEA believes the legitimate market for MAPA for the legitimate manufacturing of P2P, methamphetamine, and amphetamine is minimal. Thus, any potential cost resulting from this regulation is minimal.

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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.
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)(37) to read as follows:

§1310.02 Substances covered.
(a) * * *
   (37) methyl alpha-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers 8795 * * * * *

3. In §1310.04:
   a. Redesignate paragraphs (g)(1)(x) through (xvi) as paragraphs (g)(1)(xi) through (xvii), respectively; and
   b. Add new paragraph (g)(1)(x).

The addition reads as follows:

§1310.04 Maintenance of records.
(g) * * *
(1) * * *
   (x) methyl alpha-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers * * * * *

4. In §1310.09, add paragraph (r) to read as follows:

§1310.09 Temporary exemption from registration.
(r) (1) Each person required under 21 U.S.C. 822 and 957 to obtain a registration to manufacture, distribute, import, or export regulated forms of methyl alpha-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement would also be provided for those persons whose application for exemption is denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons would remain in effect until DEA takes final action on their registration application.

5. In §1310.12, in the Table of Concentration Limits under List I Chemicals in paragraph (c), add an entry for “methyl alpha-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate)” in alphabetical order to read as follows:

§1310.12 Exempt chemical mixtures.
(c) * * *

<table>
<thead>
<tr>
<th>DEA chemical code No.</th>
<th>Concentration</th>
<th>Special conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>methyl alpha-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers</td>
<td>* * * *</td>
<td>Chemical mixtures containing any amount of MAPA and its optical isomers are not exempt.</td>
</tr>
</tbody>
</table>

DEPARTMENT OF LABOR
Occupational Safety and Health Administration
29 CFR Parts 1910, 1915, 1917, 1918, 1926, and 1928
[Docket No. OSHA–2021–007]

COVID–19 Vaccination and Testing; Emergency Temporary Standard; Ratification of Department’s Actions

AGENCY: Occupational Safety and Health Administration, Department of Labor (DOL).

ACTION: Ratification.

SUMMARY: The Department of Labor is publishing notification of the Secretary of Labor’s ratification of a rule.

DATES: The ratification was signed on November 12, 2021.

FOR FURTHER INFORMATION CONTACT:
General information and press inquiries: Contact Frank Meilinger, OSHA Office of Communications, U.S. Department of Labor; telephone (202) 693–1999; email: OSHAComms@dol.gov.
For technical inquiries: Contact Andrew Levinson, OSHA Directorate of Standards and Guidance, U.S. Department of Labor; telephone (202) 693–1950; email: ETS@dol.gov.