DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-1395]

Designation of P2P Methyl Glycidic Acid as a List I Chemical

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration is proposing the control of the chemical 2-methyl-3-phenyloxirane-2-carboxylic acid (also known as P2P methyl glycidic acid and BMK glycidic acid) and its esters, its optical and geometric isomers, its salts, salts of its optical and geometric isomers and its esters, and any combination thereof, whenever the existence of such is possible, as a list I chemical under the Controlled Substances Act (CSA). P2P methyl glycidic acid is important to the manufacture of the schedule II controlled substances phenylacetone (also known as phenyl-2-propanone or P2P), methamphetamine, and amphetamine, and it is used in clandestine laboratories to illicitly manufacture these controlled substances. If finalized, this proposed rule would subject handlers of P2P methyl glycidic acid to the chemical regulatory provisions of the CSA and its implementing regulations. This rulemaking does not establish a threshold for domestic and international transactions of P2P methyl glycidic acid. As such, all transactions of P2P methyl glycidic acid, regardless of size, shall be regulated. In addition, chemical mixtures containing P2P methyl glycidic acid are not exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of P2P methyl glycidic acid

shall be regulated pursuant to the CSA. However, manufacturers may submit an application for exemption for those mixtures that do not qualify for automatic exemption.

DATES: Comments must be submitted electronically or postmarked on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ‘‘Docket No. DEA–1395’’ on all electronic and written correspondence, including any attachments.

- *Electronic comments*: The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to https://www.regulations.gov and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments*: Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment, in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

- *Paperwork Reduction Act Comments*: All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to Docket No. DEA-1395.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362– 3249. As required by 5 U.S.C. 553(b)(4), a summary of this proposed rule may be found in the docket for this rulemaking at *http://www.regulations.gov*.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. DEA generally will make comments available for public inspection online at *http://www.regulations.gov*. Such information includes personal or business identifiers (such as name, address, state or Federal identifiers, etc.) voluntarily submitted by the commenter. Generally, all information voluntarily submitted by the commenter, unless clearly marked as Confidential Information in the method described below, will be publicly posted. Comments may be submitted anonymously. The Freedom of Information Act applies to all comments received.

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want made publicly available should submit two copies of the comment. One copy must be marked "CONTAINS CONFIDENTIAL INFORMATION" and should clearly identify all PII or business information the commenter does not want to be made publicly available, including any supplemental materials. DEA will review this copy,

including the claimed PII and confidential business information, in its consideration of comments. The second copy should be marked "TO BE PUBLICLY POSTED" and must have all claimed confidential PII and business information already redacted. DEA will post only the redacted comment on *http://www.regulations.gov* for public inspection.

For easy reference, an electronic copy of this document and supplemental information to this proposed scheduling action are available at *http://www.regulations.gov*.

Legal Authority

The Controlled Substances Act (CSA) gives the Attorney General the authority to specify, by regulation, chemicals as list I chemicals.[1] 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."[2] The current list of all listed chemicals is published at 21 CFR 1310.02. 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). DEA regulations set forth the process by which DEA may add a chemical as a listed chemical. As set forth in 21 CFR 1310.02(c), the agency may do so by publishing a final rule in the *Federal Register* following a published notice of proposed rulemaking with at least 30 days for public comments.

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

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[1] 21 U.S.C. 802(34).
[2] *Id.*

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

By letter dated June 6, 2022, in accordance with Article 12, paragraph 6 of the 1988 Convention, the Secretary-General of the United Nations informed the United States that the chemicals P2P methyl glycidic acid and specific esters of P2P methyl glycidic acid, including their optical isomers, were added to Table I of the 1988 Convention. This letter was prompted by a decision of the United Nations Commission on Narcotic Drugs (CND) to add P2P methyl glycidic acid and specific esters of P2P methyl glycidic acid to Table I during its 67th Session on March 19, 2024. As discussed above, the United States is a party to the 1988 Convention and has certain obligations pursuant to Article 12. By designating P2P methyl glycidic acid, as well as its esters and their optical and geometric isomers, as list I chemicals, the United States will fulfill its obligations under the 1988 Convention.

P2P methyl glycidic acid 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. Throughout the 1970s, methamphetamine was illicitly produced in the United States, primarily with the precursor chemical P2P. In response to the illicit use of P2P, DEA controlled P2P as a schedule II controlled substance in 1980 pursuant to the "immediate precursor" provisions of the CSA, specifically 21 U.S.C. 811(e).[3] Clandestine laboratory operators

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[3] *Schedules of Controlled Substances; Schedule II Placement of Phenylacetone; (Phenyl-2-propanone, P2P, benzyl methyl ketone, methyl benzyl ketone)*, 44 FR 71822 (Dec. 12, 1979).

have circumvented this control by developing a variety of synthetic methods for producing P2P.

Congress and DEA responded by placing controls on certain chemicals used in the illicit production of P2P, such as phenylacetic acid (and its salts and esters), acetic anhydride, benzyl cyanide, benzaldehyde, and nitroethane.[4,5] However, clandestine laboratory operators circumvented these controls by using alternative chemicals that avoid the production of P2P—i.e., ephedrine and pseudoephedrine for the production of methamphetamine, and phenylpropanolamine for the production of amphetamine. This led Congress and DEA to place stringent controls on the manufacture, distribution, importation, and exportation of ephedrine (its salts, optical isomers, and salts of optical isomers), pseudoephedrine, and phenylpropanolamine (controlled as list I chemicals), and pharmaceutical products containing these chemicals through the Combat Methamphetamine Epidemic Act of 2005 (Pub. L. 109-117), the Methamphetamine Production Prevention Act of 2008 (Pub. L. 110-415), and the Combat Methamphetamine Act of 2010 (Pub. L. 111-268).[6]

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[4] On November 18, 1988, Congress enacted the Chemical Diversion and Trafficking Act (Subtitle A of Title VI of Pub. L. 100-690).

[5] Under 21 CFR 1310.02(a), benzaldehyde, benzyl cyanide, nitroethane, and phenylacetic acid (including its salts and esters) are list I chemicals. Under 21 CFR 1310.02(b), acetic anhydride is a list II chemical.

[6] DEA implemented the Combat Methamphetamine Epidemic Act of 2005, the Methamphetamine Production Prevention Act of 2008, and the Combat Methamphetamine Enhancement Act of 2010 in a series of interim and final rules. *See Implementation of the Combat Methamphetamine Epidemic Act of 2005; Notice of Transfers Following Importation or Exportation*, 72 FR 17401 (Apr. 9, 2007); *Implementation of the Combat Methamphetamine Epidemic Act of 2005; Notice of Transfers Following Importation or Exportation; Temporary Stay of Certain Provisions*, 72 FR 28601 (May 22, 2007); *Import and Production Quotas for Certain List I Chemicals*, 73 FR 73549 (Dec. 3, 2008); *Combat Methamphetamine Epidemic Act of 2005: Fee for Self-Certification for Regulated Sellers of Scheduled Listed Chemical Products*, 73 FR 79318 (Dec. 29, 2008); *Registration Requirements for Importers and Manufacturers of Prescription Drug Products Containing Ephedrine, Pseudoephedrine, or Phenylpropanolamine*, 75 FR 4973 (Feb. 1, 2010); *Information on Foreign Chain of Distribution for Ephedrine, Pseudoephedrine, and Phenylpropanolamine*, 75 FR 10168 (Mar. 5, 2010); *Removal of Thresholds for the List I Chemicals Pseudoephedrine and Phenylpropanolamine*, 75 FR 38915 (July 7, 2010); *Self-Certification and Employee Training of Mail-Order Distributors of Scheduled Listed Chemical Products*, 76 FR 20518 (Apr. 13, 2011); *Implementation of the Methamphetamine Production Prevention Act of 2008*, 76 FR 74696 (Dec. 1, 2011).

With the growing problem of illicit drug production and the issue of precursor chemical controls gaining global attention, the international community soon took similar measures. Article 12 of the 1988 Convention first established international controls on precursors. Article 12 established two categories of controlled illicit drug precursor substances: Table I and Table II.[7] International efforts to prevent the illicit production of amphetamine-type stimulants (including amphetamine and methamphetamine), and international control of precursors have since made significant progress.

Two international entities have played a crucial role in this effort—the CND and the International Narcotics Control Board (INCB). The CND meets annually to consider and adopt a range of decisions and resolutions related to international drug control treaties, including the 1988 Convention. The INCB is an independent quasi-judicial expert body for the implementation of the international drug control treaties, including the 1988 Convention. Previously, the CND has voted to include methamphetamine and amphetamine precursor chemicals, including *alpha*-phenylacetoacetonitrile (APAAN),[8] 3,4-MDP2P methyl glycidicate, 3,4-MDP2P glycidic acid, *alpha*-phenylacetoacetamied (APAA),[9] and methyl *alpha*-phenylacetoacetate (MAPA) under the 1988 Convention.[10] The DEA subsequently added these chemicals as list I chemicals to the CSA.[11]

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[7] Table I and Table II are annexed to the Convention.
[8] APAAN was added to Table I of the 1988 Convention at the 57th Session of the CND, which took place in March 2014.
[9] APAA, 3,4-MDP2P glycidic acid, and 3,4-MDP2P methyl glydicate were added to Table I of the 1988 Convention at the 62nd Session of the CND
[10] MAPA was added to Table I of the 1988 Convention at the 63rd Session of the CND
[11] *Designation of Alpha-Phenylacetoacetonitrile (APAAN), a Precursor Chemical Used in the Illicit Manufacture of Phenylacetone, Methamphetamine, and Amphetamine, as a List I Chemical*, 82 FR 32457 (July 14, 2017); *Designation of Methyl alpha-phenylacetoacetate, a Precursor Chemical Used in the Illicit Manufacture of Phenylacetone, Methamphetamine, and Amphetamine, as a List I Chemical*, 86 FR 64362 (Nov. 18, 2021); *Designation of 3,4-MDP-2-P methyl glycidate (PMK glycidate), 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid), and alpha-phenylacetoacetamide (APAA) as List I Chemicals*, 86 FR 24703 (May 10, 2021); *Designation of 3,4-MDP-2-P Methyl Glycidate (PMK Glycidate), 3,4-MDP-2-P Methyl Glycidic Acid (PMK Glycidic Acid), and Alpha-Phenylacetoacetamide (APAA) as List I Chemicals; Correction*, 86 FR 30169 (June 7, 2021).

In response to domestic and international controls on amphetamine and methamphetamine precursors, clandestine laboratory operators have continued to explore alternate methods of making these illicit drugs, including developing techniques to manufacture their own precursors and diverting other precursors to produce these precursors. The INCB noted the use of P2P methyl glycidic acid and its esters as precursors for the production of P2P.[12] The INCB began reporting the emergence of P2P methyl glycidic acid in 2012, the emergence of methyl ester of P2P methyl glycidic acid in 2016, and the emergence of ethyl ester of P2P methyl glycidic acid in 2023.[13] P2P methyl glycidic acid does not have any legitimate use, and it has not been widely traded through legitimate channels. Clandestine laboratory operators currently use P2P methyl glycidic acid to manufacture P2P, which they then convert to methamphetamine and amphetamine.

P2P Methyl Glycidic Acid

P2P methyl glycidic acid is known as 2-methyl-3-phenyloxirane-2-carboxylic acid; BMK glycidic acid; and CAS number: 25547-51-7. Since 2012, there have been 113 reports of the P2P methyl glycidic acid sodium salt and 117 reports of P2P methyl glycidic acid through the Precursors Incident Communication System (PICS).[14] More than 47 metric tons of P2P methyl glycidic acid sodium salt and 51 metric tons of P2P methyl glycidic acid were seized. Reports identified China as the country of origin for 64 out of the 103 incidents (for example, seizures, stopped shipments, diversions, etc.) where country of origin was indicated in the incident report. The majority of the incidents were reported in the Netherlands. Since November 2012, through PICS, the INCB reported an increase in the frequency of seizures and amounts seized reported for

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[12] Statement by Professor Jallal Toufiq, President, INCB, 67th Session of the, Mar. 19, 2024.
[13] *Id.*
[14] PICS is a worldwide, real-time, on-line tool for communication and information sharing between national authorities on precursor incidents to include seizures, stopped shipments, diversion and diversion attempts, illicit laboratories and associated equipment. Queried July 1, 2024, https://pics.incb.org/ .

the sodium salt of P2P methyl glycidic acid. Further, since 2022, INCB reported an increase in frequency and amounts of incidents for P2P methyl glycidic acid, from 35 incidents in 2022 to 68 incidents in 2023.[15]

The INCB notes that P2P methyl glycidic acid, including its salts, does not have any legitimate use.[16] DEA has not identified any known legitimate use for P2P methyl glycidic acid, other than in small amounts for research, development, and laboratory analytical purposes. Due to the lack of industrial uses of P2P methyl glycidic acid, the chemical has not been widely available from legitimate chemical suppliers. Since 2012, however, there have been large international seizures of P2P methyl glycidic acid and its salts, primarily in Europe, which suggest there is a ready supply of P2P methyl glycidic acid from international chemical manufacturers. The only use for a large quantity of P2P methyl glycidic acid of which DEA is aware is as a primary precursor for conversion to P2P, and subsequent conversion to amphetamine or methamphetamine.

DEA has determined that P2P methyl glycidic acid is now readily available from commercial chemical suppliers and has identified potential suppliers in the United States, China, Austria, Hong Kong, the Netherlands, Slovakia, Switzerland, and the United Kingdom.

Since 2016, there have been 12 reports through PICS of the methyl ester of P2P methyl glycidic acid and four reports of the ethyl ester of P2P methyl glycidic acid, totaling more than seven metric tons of the methyl ester of P2P methyl glycidic acid seized and 986 kg of the ethyl ester of P2P methyl glycidic acid seized.[17] China was reported as the alleged origin country for all incidents where the origin country was reported. The majority of the incidents were reported in the Netherlands. The INCB

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[15] *Id.*
[16] Statement by Professor Jallal Toufiq, President, INCB, 67th Session of the CND (Mar. 19, 2024), at 2b.
[17] PICS system queried July 1, 2024, https://pics.incb.org/.

reported an increase in the frequency of seizures and amounts seized reported through PICS since November 2016.[18]

DEA is concerned about the ease with which P2P methyl glycidic acid and its esters serve as precursor chemicals for illicit controlled substance production and with the international trafficking in this chemical. The international community shares this concern. The INCB found that P2P methyl glycidic acid and its esters are "highly suitable for the illicit manufacture of P2P."[19] Based in part on the findings of the INCB, and as noted above, the CND has added P2P methyl glycidic acid and select esters of P2P methyl glycidic acid to Table I of the 1988 Convention. Therefore, DEA is proposing the designation of P2P methyl glycidic acid, including its optical and geometric isomers, its esters, its salts, and salts of its optical and geometric isomers and its esters, and any combination thereof, as list I chemicals.

Proposed Designation of P2P Methyl Glycidic Acid and Its Esters, Its Optical and Geometric Isomers, Its Salts, Salts of Its Optical and Geometric Isomers and Its Esters, and Any Combination Thereof as List I Chemicals

For the reasons discussed above, the Administrator of DEA finds that P2P methyl glycidic acid is used in the manufacture of controlled substances (*i.e.*, schedule II substances P2P, methamphetamine, and amphetamine) in violation of the CSA and is important to the manufacture of these controlled substances. Clandestine laboratory operators are using P2P methyl glycidic acid as a precursor material for the illicit manufacture of P2P, methamphetamine, and amphetamine. Therefore, the Administrator proposes the designation of P2P methyl glycidic acid as a list I chemical.

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[18] *Id.*

[19] Statement by Professor Jallal Toufiq, President, International Narcotics Control Board, 67th Session of the Commission on Narcotic Drugs, March 19, 2024, at 5.

If finalized, handlers of P2P methyl glycidic acid would become subject to the chemical regulatory provisions of the CSA, including 21 CFR parts 1309, 1310, 1313, and 1316. Because there are no legitimate industrial uses for P2P methyl glycidic acid, this action does not propose the establishment of a threshold for domestic and import transactions of P2P methyl glycidic acid in accordance with the provisions of 21 CFR 1310.04(g). Therefore, DEA is proposing that all P2P methyl glycidic acid transactions, regardless of size, would be regulated transactions as defined in 21 CFR 1300.02(b). As such, if finalized, all P2P methyl glycidic acid transactions would be subject to recordkeeping, reporting, import and export controls, and other CSA chemical regulatory requirements. In addition, each regulated bulk manufacturer must submit manufacturing, inventory, and use data on an annual basis, in accordance with 21 CFR 1310.05(d).

Chemical Mixtures of P2P Methyl Glycidic Acid

This rulemaking also proposes that chemical mixtures containing P2P methyl glycidic acid would not be exempt from regulatory requirements at any concentration, unless a manufacturer submits to DEA an application for exemption of such 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). Because there are no legitimate industrial uses for P2P methyl glycidic acid, regulation of chemical mixtures containing any amount of P2P methyl glycidic acid is necessary to prevent the illicit extraction, isolation, and use of P2P methyl glycidic acid. Therefore, all chemical mixtures containing any quantity of P2P methyl glycidic acid would be subject to control under the CSA, unless a manufacturer of P2P methyl glycidic acid is granted an exemption by the application process in accordance with 21 CFR 1310.13. This rule proposes the modification of the "Table of Concentration Limits" in 21 CFR 1310.12(c) to reflect the fact that chemical mixtures containing any amount of P2P methyl glycidic acid are subject to CSA chemical control provisions.

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.[20] 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

If finalized as proposed, the designation of P2P methyl glycidic acid as a list I chemical would subject handlers (manufacturers, distributors, importers, and exporters) and proposed handlers to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of a list I chemical. Upon the effective date of the final rule, persons potentially handling P2P methyl glycidic acid, including regulated chemical mixtures containing P2P methyl glycidic acid, would be required to comply with the following list I chemical regulations:

1. *Registration*. Any person who handles (manufactures, distributes, imports, or exports), or proposes to engage in such handling of, P2P methyl glycidic acid or a chemical mixture containing P2P methyl glycidic acid would be required to 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

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[20] 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").

exporting of P2P methyl glycidic acid.[21] Further, a separate registration would be 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.[22]

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.[23] Under DEA implementing regulations, the warehouse in question would need to receive the list I chemical from a DEA registrant and would only be able to distribute the list I chemical back to the DEA registrant and registered location from which it was received.[24] A warehouse that distributes list I chemicals to persons other than the registrant and registered location from which they were obtained would be conducting distribution activities and so would be required to register as such.

Upon publication of a final rule, any person manufacturing, distributing, importing, or exporting P2P methyl glycidic acid or a chemical mixture containing P2P methyl glycidic acid would become subject to the registration requirement under the CSA. DEA recognizes, however, that it is not possible for persons who are subject to the registration requirements to immediately complete and submit an application for registration and for DEA to immediately issue registrations for those activities. Therefore, to allow any continued legitimate commerce in P2P methyl glycidic acid, DEA is proposing to establish in 21 CFR 1310.09 a temporary exemption from the registration requirement for persons desiring to engage in activities with P2P methyl glycidic acid, provided that DEA receives a properly completed application for registration on or before 30 days after publication of a final rule implementing

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[21] 21 CFR 1309.21.
[22] 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).
[23] 21 U.S.C. 822(c)(2), 957(b)(1)(B).
[24] *See* 21 CFR 1309.23(b)(1).

regulations regarding P2P methyl glycidic acid. The temporary exemption for such persons would remain in effect until DEA takes final action on their application for registration or application for exemption of a chemical mixture.

The temporary exemption would apply solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, would be applicable as of the effective date of the final rule. Therefore, all transactions of P2P methyl glycidic acid and chemical mixtures containing P2P methyl glycidic acid would be regulated while an application for registration or exemption is pending. This is necessary because a delay in regulating these transactions could result in increased diversion of chemicals desirable to drug traffickers.

Additionally, the temporary exemption for registration does not suspend applicable Federal criminal laws relating to P2P methyl glycidic acid, nor does it supersede State or local laws or regulations. All handlers of P2P methyl glycidic acid must comply with applicable State and local requirements in addition to the CSA regulatory controls.

2. *Records and Reports*. Every DEA registrant would be required to maintain records and submit reports to DEA with respect to P2P methyl glycidic acid 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, such 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 would be required to submit manufacturing, inventory, and use data on an annual basis.[25] Existing standard

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[25] 21 CFR 1310.05(d).

industry reports containing the required information would be acceptable, provided the information is separate or readily retrievable from the report.

Regulated persons would need to comply with the CSA and its implementing regulations requiring 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 would need to 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.[26]

3. *Importation and Exportation*. All importation and exportation of P2P methyl glycidic acid would need to 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 would be required to 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, would 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.[27]

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[26] 21 USC 830(b); 21 CFR 1310.05(a), (b).
[27] 21 U.S.C. 880.

6. *Liability*. Any activity involving P2P methyl glycidic acid not authorized by, or in violation of, the CSA would be unlawful, and would subject the person to administrative, civil, and/or criminal action.

REGULATORY ANALYSES

Executive Orders 12866, 13563, 14192, and 14294 (Regulatory Review)

This proposed rule was developed in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 14192. 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. DEA scheduling actions are not subject to E.O. 14192, Unleashing Prosperity Through Deregulation.

Executive Order 14294 specifies that all notices of proposed rulemaking (NPRMs) and final rules published in the Federal Register, the violation of which may constitute criminal regulatory offenses, should include a statement identifying that the rule or proposed rule is a criminal regulatory offense, the authorizing statute, and the mens rea requirement for each element of the offense. This final rule does not involve a criminal regulatory offense and thus E.O. 14294 does not apply.

DEA has determined that this proposed rule is not a "significant regulatory action" under E.O. 12866, section 3(f). Accordingly, this rule was not reviewed by the Office of Information and Regulatory Affairs.

If finalized as proposed, P2P methyl glycidic acid would be subject to all of the regulatory controls as well as the administrative, civil, and criminal sanctions applicable to the manufacturing, distributing, importing, and exporting of list I chemicals. As discussed in this notice, P2P methyl glycidic acid is used in, and is important to, the illicit

manufacture of the schedule II-controlled substances P2P, methamphetamine, and amphetamine.

DEA has searched information in the public domain for any legitimate uses of this chemical. Other than the small amounts for research, development, and laboratory analytical purposes, DEA has not documented any industrial use for P2P methyl glycidic acid except for it being a chemical intermediate in the production of the schedule II substances P2P, methamphetamine, and amphetamine. Based on the review of the established aggregate production quota for P2P (100 grams for 2024), legal conversion of P2P methyl glycidic acid 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, P2P methyl glycidic acid is used for the illicit manufacturing of P2P, methamphetamine, and amphetamine.

DEA cannot rule out the possibility that minimal quantities of P2P methyl glycidic acid are used for the manufacturing of legitimate P2P. However, if there are any quantities of P2P methyl glycidic acid used for the manufacturing of legitimate P2P, the quantities are believed to be minimal. DEA welcomes any public comment on these quantities and their economic significance.

DEA evaluated the costs and benefits of this proposed action.

Costs

DEA believes the market for P2P methyl glycidic acid for the legitimate manufacturing of pharmaceutical amphetamine or methamphetamine is minimal. As stated above, the only use for P2P methyl glycidic acid 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 P2P methyl glycidic acid for the production of legitimate P2P, methamphetamine, and amphetamine, if they exist at all, would incur costs if this proposed rule were finalized. The primary costs associated with

this proposed rule would be the annual registration fees for manufacturers ($3,699) and for distributors, importers, and exporters ($1,850). However, any manufacturer that uses P2P methyl glycidic acid 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. As there are different forms of handling the scheduled substances versus the list I chemical (distribution of P2P, methamphetamine, and amphetamine versus exporting P2P methyl glycidic acid), this could require a separate registration for the different handling of the substances. If an entity is already registered to handle, manufacture, import, or export a scheduled substance, the entity would not need an additional registration for the list I chemical, provided it is handling the list I chemical in the same manner that it is registered for the scheduled substance, or as a coincident activity permitted by § 1309.21(c). Even with the possibility of these additional registrations, DEA believes that the cost would be minimal.

DEA has identified nine domestic suppliers of P2P methyl glycidic acid. It is difficult to estimate the quantity of P2P methyl glycidic acid these suppliers distribute. Chemical distributors often have items in their catalog while not actually having any material level of sales. If this proposed rule is finalized, suppliers for the legitimate use of P2P methyl glycidic acid, if any, are expected to choose the least-cost option, which might include stopping the selling of minimal quantities of P2P methyl glycidic acid, rather than incurring the registration cost. Because DEA believes the quantities of P2P methyl glycidic acid supplied for the legitimate manufacturing of P2P, methamphetamine, and amphetamine are minimal, DEA estimates that the cost of foregone sales is minimal; and thus, the cost of this proposed rule is minimal. DEA welcomes any public comment regarding this estimate.

This analysis excludes consideration of any economic impact to those businesses that facilitate the manufacture and distribution of P2P methyl glycidic acid for the production of manufacturing illicit P2P, methamphetamine, and amphetamine. As a law enforcement organization and as a matter of principle, DEA believes considering the economic utility of facilitating the manufacture of illicit P2P, methamphetamine, and amphetamine would be improper.

Benefits

Controlling P2P methyl glycidic acid is expected to prevent, curtail, and limit the unlawful manufacturing and distribution of the controlled substances P2P, methamphetamine, and amphetamine. As a list I chemical, handling of P2P methyl glycidic acid would require registration with DEA, various controls, and monitoring as required by the CSA. This proposed rule is also expected to assist in preventing the possible theft or diversion of P2P methyl glycidic acid from any legitimate firms. DEA also believes control is necessary to prevent unscrupulous chemists from synthesizing P2P methyl glycidic acid and selling it (as unregulated material) through the internet and other channels, to individuals who may wish to acquire unregulated chemical intermediates for the purpose of manufacturing illicit P2P, methamphetamine, and amphetamine.

In summary, DEA conducted a qualitative analysis of costs and benefits. DEA believes this proposed action, if finalized, would minimize the diversion of P2P methyl glycidic acid. DEA believes the market for P2P methyl glycidic acid for the legitimate manufacturing of P2P, methamphetamine, and amphetamine is minimal. Therefore, any potential cost as a result of this regulation is minimal.

Executive Order 12988, Civil Justice Reform

This proposed 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 proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed 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 proposed 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 Administrator, in accordance with the Regulatory Flexibility Act (RFA),[28] has reviewed this proposed 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, if this rule is finalized as proposed, P2P methyl glycidic acid would be 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. P2P methyl glycidic acid 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 P2P methyl glycidic acid, other than its role as a chemical intermediate in the production of P2P, methamphetamine, and amphetamine. Based on the review of established aggregate production quota for P2P, 100 grams for

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[28] 5 U.S.C. 601-612.

2024, legal conversion of P2P methyl glycidic acid in the United States, if it takes place at all, is limited to small, gram quantities. Therefore, DEA believes the vast majority, if not all, of P2P methyl glycidic acid is used for the illicit manufacturing of P2P, methamphetamine, and amphetamine. The primary costs associated with this proposed rule would be the annual registration fees ($3,699 for manufacturers and $1,850 for distributors, importers, and exporters), but those registration fees would only be applicable if they choose as part of their business plan to continue to handle P2P methyl glycidic acid and that may not be economically worthwhile if they only had been handling small amounts. Additionally, any manufacturer that does use P2P methyl glycidic acid for legitimate P2P, methamphetamine, and amphetamine production would already be registered with DEA and have all security and other handling processes in place, resulting in minimal cost.

DEA has identified nine domestic suppliers of P2P methyl glycidic acid. It is difficult to estimate the quantity of P2P methyl glycidic acid these suppliers distribute. Chemical distributors often have items in their catalog while not actually having any material level of sales. Based on the review of established aggregate production quota for P2P (100 grams for 2024), legal conversion of P2P methyl glycidic acid to P2P in the United States is limited to small gram quantities. DEA believes any quantity of sales of P2P methyl glycidic acid from these distributors for legitimate P2P manufacturing is minimal. Therefore, DEA estimates the cost of this rule on any affected small entity is minimal. DEA welcomes any public comment regarding this estimate. Based on these factors, DEA projects that this rule, if promulgated, will not result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the RFA section above, DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995

(UMRA), 2 U.S.C. 1501 *et seq.*, 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 provisions of UMRA.

Paperwork Reduction Act

This proposed action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501-3521. This proposed action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations.

List of Subjects in 21 CFR Part 1310

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

Accordingly, for the reasons set forth in the preamble, DEA proposes to amend 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)(41) to read as follows:

§ 1310.02 Substances covered.

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(a) * * *

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(41) P2P methyl glycidic acid (2-methyl-3-phenyloxirane-2-carboxylic acid; BMK glycidic acid) and its esters, its optical and geometric isomers, its salts, salts of its optical and geometric isomers and its esters, and any combination thereof, whenever the existence of such is possible, including the following: (i) Methyl ester of P2P methyl glycidic acid (methyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P methyl glycidicate; BMK methyl glycidicate) (ii) Ethyl ester of P2P methyl glycidic acid (ethyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P ethyl glycidicate; BMK ethyl glycidicate) (iii) Propyl ester of P2P methyl glycidic acid (propyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P propyl glycidicate; BMK propyl glycidicate) (iv) Isopropyl ester of P2P methyl glycidic acid (isopropyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P isopropyl glycidicate; BMK isopropyl glycidicate) (v) Butyl ester of P2P methyl glycidic acid (butyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P butyl glycidicate; BMK butyl glycidicate) (vi) Isobutyl ester of P2P methyl glycidic acid (isobutyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P isobutyl glycidicate; BMK isobutyl glycidicate)	8526

(vii) sec-Butyl ester of P2P methyl glycidic acid (sec-butyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P sec-butyl glycidicate; BMK sec-butyl glycidicate (viii) tert-Butyl ester of P2P methyl glycidic acid (tert-butyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P tert-butyl glycidicate; BMK tert-butyl glycidicate	

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3. In §1310.04:

a. Redesignate paragraphs (g)(1)(xvi) through (xx) as paragraphs (g)(1)(xvii) through (xxi), respectively; and

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

The addition reads as follows:

§ 1310.04 Maintenance of records.

* * * * *

(g) * * *

(1) * * *

(xvi) P2P methyl glycidic acid (2-methyl-3-phenyloxirane-2-carboxylic acid; BMK glycidic acid) and its esters, its optical and geometric isomers, its salts, salts of its optical and geometric isomers and its esters, and any combination thereof, whenever the existence of such is possible

* * * * *

4. Amend § 1310.09 by adding new paragraph (t) to read as follows:

§ 1310.09 Temporary exemption from registration.

* * * * *

(t)(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 P2P methyl glycidic acid (2-methyl-3-phenyloxirane-2-carboxylic acid; also known as BMK glycidic acid) and its esters, its optical and geometric isomers, its salts, salts of its optical and geometric isomers and its esters, and any combination thereof, whenever the existence of such is possible, including regulated chemical mixtures pursuant to section 1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing regulated forms of P2P methyl glycidic acid pursuant to section 1310.13 on or before 30 days after the publication of a rule finalizing this action. The exemption would remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture containing regulated forms of P2P methyl glycidic acid (2-methyl-3-phenyloxirane-2-carboxylic acid; BMK glycidic acid) and its esters, its optical and geometric isomers, its salts, salts of its optical and geometric isomers and its esters, and any combination thereof, whenever the existence of such is possible, 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.

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5. In § 1310.12, the Table of Concentration Limits in paragraph (c) is amended by adding an entry for P2P methyl glycidic acid (2-methyl-3-phenyloxirane-2-carboxylic acid; BMK glycidic acid) and its esters, its optical and geometric isomers, its salts, salts of its optical and geometric isomers and its esters, and any combination thereof, whenever the existence of such is possible in alphabetical order to read as follows:

§ 1310.12 Exempt chemical mixtures.

* * * * *

(c) * * *

TABLE OF CONCENTRATION LIMITS

	DEA chemical code number	Concentration	Special conditions
*******			
P2P methyl glycidic acid (2-methyl-3-phenyloxirane-2-carboxylic acid; BMK glycidic acid) and its esters, its optical and geometric isomers, its salts, salts of its optical and geometric isomers and its esters, and any combination thereof, whenever the existence of such is possible……	8526	Not exempt at any concentration	Chemical mixtures containing any amount of P2P methyl glycidic acid 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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