



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-1189]

Designation of Propionyl Chloride as a List I Chemical

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration is finalizing the control of propionyl chloride as a list I chemical under the Controlled Substances Act (CSA). Propionyl chloride is used in the illicit manufacture of the controlled substances fentanyl, fentanyl analogues, and fentanyl-related substances, and it is important to the manufacture of these substances. This final rule subjects handlers of propionyl chloride to the chemical regulatory provisions of the CSA and its implementing regulations.

DATES: This rulemaking will become effective on [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Persons seeking registration must apply before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER] to continue their business pending final action by DEA on their application.

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SUPPLEMENTARY INFORMATION:

The Drug Enforcement Administration (DEA) is extremely concerned with the recent increase in the illicit manufacture and distribution of fentanyl. Therefore, on October 12, 2023, DEA published an Advanced Notice of Proposed Rulemaking (ANPRM) soliciting comments on the legitimate use of propionyl chloride in industry. On June 3, 2025, DEA

published a Notice of Proposed Rulemaking (NPRM) to control the precursor chemical propionyl chloride as a list I chemical.¹ This rulemaking finalizes that NPRM.

This action subjects handlers of propionyl chloride 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 propionyl chloride. As such, all transactions involving propionyl chloride, regardless of size, shall be regulated and are subject to control under the CSA. In addition, chemical mixtures containing propionyl chloride are not exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of propionyl chloride shall be regulated pursuant to the CSA.

Legal Authority

The CSA gives the Attorney General the authority to specify, by regulation, chemicals as list I chemicals.² A “list I chemical” is defined as “a chemical that is used in manufacturing a controlled substance in violation of [the CSA] and is important to the manufacture of the controlled substance.”³ 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 NPRM with at least 30 days for public comments.

Background

¹ *Designation of Propionyl Chloride as a List I Chemical*, 90 FR 23483 (June 3, 2025).

² 21 U.S.C. 802(34).

³ *Id.*

The clandestine manufacture of fentanyl, fentanyl analogues, and fentanyl-related substances remains extremely concerning as the distribution of illicit fentanyl, fentanyl analogues, and fentanyl-related substances continues to drive drug-related overdose deaths in the United States. Fentanyl is a synthetic opioid and was first synthesized in Belgium in the late 1950s. Fentanyl was introduced into medical practice and is approved for medical practitioners in the United States to prescribe lawfully for anesthesia and analgesia. Yet, due to its pharmacological effects, fentanyl can be used as a substitute for heroin, oxycodone, and other opioids. Therefore, due to its currently accepted medical use in treatment in the United States, DEA controls fentanyl as a schedule II controlled substance despite its high potential for abuse and the possibility that abuse may lead to severe psychological or physical dependence.⁴ Moreover, there are a substantial number of fentanyl analogues and fentanyl-related substances that are being distributed on the illicit drug market. Illicit manufacturers attempt to utilize unregulated precursor chemicals to evade law enforcement detection and precursor chemical controls to manufacture fentanyl, fentanyl analogues, and fentanyl-related substances. This strategy allows for the synthesis of a variety of fentanyl analogues and fentanyl-related substances by making slight modifications to the core fentanyl structure while maintaining the same synthetic methodology used to synthesize fentanyl, fentanyl analogues, and fentanyl-related substances.

The unlawful trafficking of fentanyl, fentanyl analogues, and fentanyl-related substances in the United States continues to pose an imminent hazard to the public safety. Since 2012, fentanyl has shown a dramatic increase in the illicit drug supply as a single substance, in mixtures with other illicit drugs (*i.e.*, heroin, cocaine, and methamphetamine), and in forms that mimic pharmaceutical preparations including prescription opiates.⁵

⁴ 21 U.S.C. 812(c) Schedule II(b)(6) and 21 CFR 1308.12(c).

⁵ National Drug Threat Assessment 2025, Drug Enforcement Administration, May 2025.

DEA has noted a significant increase in overdoses and overdose fatalities from fentanyl, fentanyl analogues, and fentanyl-related substances in the United States in recent years, with a slight decrease in 2023. According to the Centers for Disease Control and Prevention (CDC), opioids, mainly synthetic opioids (which include fentanyl), are predominantly responsible for drug overdose deaths in recent years. According to CDC WONDER,⁶ drug overdose deaths involving synthetic opioids (excluding methadone) in the United States increased from 36,359 in 2019 to 56,516 in 2020; 70,601 in 2021; and 73,838 in 2022 with only a slight decrease to 72,776 in 2023; and provisionally 48,018 in 2024.⁷ While the total number of overdose deaths have been declining (overdose deaths peaked in 2022 with 107,941 deaths; then decreased to 105,007 in 2023; and provisionally decreased to 79,848 in 2024), opioids continue to be the drug class associated with the largest number of overdose deaths. Overdose fatalities involving synthetic opioids coincides with a dramatic increase in law enforcement encounters of fentanyl, fentanyl analogues, and fentanyl-related substances. According to the National Forensic Laboratory Information System (NFLIS-Drug),⁸ reports from forensic laboratories of drug items containing fentanyl, fentanyl analogues, and fentanyl-related substances increased dramatically since 2016, as shown in Table 1 (2025 data is still being reported).

⁶ Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Data are from the final Multiple Cause of Death Files, 2018-2024, and from provisional data for years 2024-2025, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at <http://wonder.cdc.gov/mcd-icd10-provisional.html> on January 27, 2026.

⁷ Provisional counts in CDC Wonder are the counts of overdose deaths prior to being finalized for a calendar year. Provisional counts of deaths are underestimated relative to final counts. This is due to the many steps involved in reporting death certificate data. When a death occurs, a certifier (e.g. physician, medical examiner or coroner) will complete the death certificate with the underlying cause of death and any contributing causes of death. In some cases, laboratory tests or autopsy results may be required to determine the cause of death.

⁸ The National Forensic Laboratory Information System (NFLIS) represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by Federal, State and local forensic laboratories in the United States. While NFLIS-Drug data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV*, 76 FR 77330, 77332 (Dec. 12, 2011). NFLIS-Drug data was queried on January 8, 2026; *2025 data is still reporting.

Table 1. Annual Reports of Fentanyl and Select Fentanyl Analogues and Fentanyl-Related Substances Identified in Drug Encounters.

Year	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025*
Annual Fentanyl Reports	37,158	61,648	90,017	108,231	126,483	166,718	177,227	183,009	154,015	89,003
Annual Reports of select fentanyl analogues and fentanyl-related substances	7,625	22,072	16,163	20,935	8,005	26,691	30,978	21,511	20,205	7,616

Role of Propionyl Chloride in the Synthesis of Fentanyl

Fentanyl, fentanyl analogues, and fentanyl-related substances are not naturally occurring substances. As such, the manufacture of these substances requires them to be produced through synthetic organic chemistry. Synthetic organic chemistry is the process in which a new organic molecule is created through one chemical reaction or a series of chemical reactions, which involve precursor chemicals. Through chemical reactions, the chemical structures of precursor chemicals are modified in a desired fashion. These chemical reaction sequences, also known as synthetic pathways, are designed to create a desired substance. Several synthetic pathways to fentanyl, fentanyl analogues, and fentanyl-related substances have been identified in clandestine laboratory settings; these include the original “Janssen method,” the “Siegfried method,” and the “Gupta method.” In response to the illicit manufacture of fentanyl, fentanyl analogues, and fentanyl-related substances using these

methods, DEA controlled *N*-phenethyl-4-piperidone (NPP);⁹ *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and its salts;¹⁰ *N*-phenylpiperidin-4-amine (4-anilinopiperidine) including its amides, halides, carbamates, salts, and any combination thereof;¹¹ and 4-piperidone (piperidin-4-one) including its acetals, amides, carbamates, salts, and salts of acetals, amides, and carbamates, and any combination thereof¹² as list I chemicals. DEA also controls 4-anilino-*N*-phenethylpiperidine (ANPP)¹³ and *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl)¹⁴ as schedule II immediate precursors to fentanyl under the CSA.

Propionyl Chloride

The original published synthetic pathway to fentanyl, known as the Janssen method, involves the list I chemical benzylfentanyl and schedule II immediate precursor norfentanyl. In this synthetic pathway, benzylfentanyl, a list I chemical under the CSA,¹⁵ is synthesized by reacting propionyl chloride with 4-anilino-1-benzylpiperidine, which is then converted to norfentanyl, the schedule II immediate precursor to fentanyl in this synthetic pathway.¹⁶ Norfentanyl is then subjected to one simple chemical reaction to complete the synthesis of fentanyl. This synthetic pathway can also be easily modified to produce fentanyl analogues and fentanyl-related substances. Propionyl chloride also serves as a precursor chemical in the Siegfried method. In this synthetic pathway, propionyl chloride is reacted with ANPP,¹⁷ the schedule II immediate precursor to fentanyl in the Siegfried method, to complete the

⁹ *Control of a Chemical Precursor Used in the Illicit Manufacture of Fentanyl as a List I Chemical*, 72 FR 20039 (Apr. 23, 2007).

¹⁰ *Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals*, 85 FR 20822 (Apr. 15, 2020).

¹¹ *Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals*, 85 FR 20822 (Apr. 15, 2020.); See Also *Designation of Halides of 4-Anilinopiperidine as List I Chemicals*, 88 FR 74352 (Oct. 31, 2023).

¹² *Designation of 4-Piperidone as a List I Chemical*, 88 FR 21902-21910 (Apr. 12, 2023).

¹³ *Control of Immediate Precursor Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance*, 75 FR 37295 (June 29, 2010).

¹⁴ *Control of the Immediate Precursor Norfentanyl Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance*, 85 FR 21320 (Apr. 17, 2020).

¹⁵ See footnote 10.

¹⁶ See footnote 13.

¹⁷ See footnote 12.

synthesis of fentanyl. This synthetic pathway can also be easily modified to produce fentanyl analogues and fentanyl-related substances. In addition to the Janssen and Siegfried methods, clandestine manufacturers are using other methods to synthesize fentanyl, one of which is known as the Gupta method. In this synthetic pathway, 4-piperidone, a list I chemical under the CSA, is used to synthesize 4-anilinopiperidine, another list I chemical under the CSA,¹⁸ which serves as an alternative precursor chemical to NPP, a list I chemical, in the synthesis of ANPP, a schedule II immediate precursor to fentanyl albeit through a different synthetic process. The resulting ANPP is reacted with propionyl chloride to manufacture the schedule II controlled substance, fentanyl. This synthetic pathway can also be easily modified to produce fentanyl analogues and fentanyl-related substances.

Propionyl chloride is attractive to illicit manufacturers because there is a lack of regulations on this chemical, it is readily available from chemical suppliers, and it can be easily used in many known synthetic pathways used for the illicit manufacture of fentanyl, fentanyl analogues, and fentanyl-related substances.

Comments Received in Response to the NPRM

In response to the June 3, 2025 NPRM, DEA received one comment in opposition to the control of propionyl chloride as a list I chemical. The commenter cited four areas of concern relating to the control of propionyl chloride.

Comment: The first concern the commenter raised was that controlling propionyl chloride as a list I chemical would disproportionately harm legitimate industries, specifically the pharmaceutical industry, the agrochemical industry, and other industries using it in their applications. The commenter mentioned propionyl chloride is used to synthesize vital medicines, it is an intermediate for crop protection agents, and can be used to produce dyes, textiles, and other products. The commenter also mentioned that even though norfentanyl is

¹⁸*Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals*, 85 FR 20822 (May 15, 2020).

an immediate precursor to fentanyl, it was only controlled as a list II chemical, which is in stark contrast to what is being proposed for the control of propionyl chloride in list I.

DEA Response: DEA appreciates the commenter's concern for the industries that may be impacted by the control of propionyl chloride as a list I chemical. To properly assess the potential effects of controlling propionyl chloride, DEA published both an ANPRM and the NPRM. These two publications requested information from industries and allowed for any interested persons to comment with their concerns.

DEA is aware that propionyl chloride may be used as an intermediate in several industrial processes, including but not limited to the synthesis of dyes, pharmaceuticals (including fentanyl), and agricultural products. Designating propionyl chloride as a list I chemical does not preclude the use of propionyl chloride for end users (i.e., those using it as an intermediate chemical or in chemical synthesis). DEA registration for list I chemicals is only for those who are manufacturing, distributing, importing, or exporting list I chemicals. It is not required for those doing synthesis, unless they are also participating in one of the forementioned activities that require registration. Therefore, unless the user is also manufacturing, distributing, importing, or exporting propionyl chloride, this action will not affect industries that may be using propionyl chloride as an intermediate in synthesis. Any potential burdens on industry are outweighed by the public health and public safety benefits of listing propionyl chloride.

In regard to controlling propionyl chloride in list I compared to the placement of norfentanyl, norfentanyl is controlled in schedule II of the CSA as an immediate precursor to fentanyl. Requirements for controlled substances in schedules I-V of the CSA,¹⁹ including immediate precursors in schedule II, are more restrictive than that of chemicals listed in list I or list II of CSA.²⁰ Controlling propionyl chloride in list I would only require those who

¹⁹ 21 CFR 1301-1308; 21 CFR 1311-1312

²⁰ 21 CFR 1309-1310; 21 CFR 1313

manufacture, distribute, import, or export propionyl chloride to register with DEA and maintain records. End users of propionyl chloride, unless they are engaged in one of the previous mentioned activities, would not be required to register with DEA. Therefore, industries who may be using propionyl chloride in legitimate industries will still be able to use propionyl chloride for research and industrial purposes and may not be required to register with DEA for the use of this chemical.

Comment: The commenter next voiced concern that this action exceeds DEA's authority and harms the U.S. economy. The commenter concluded that the United States is a net importer of propionyl chloride, and, therefore, DEA is attempting to regulate foreign commerce, which is an authority delegated exclusively to Congress.

DEA Response: DEA appreciates the commenter's concerns. In the CSA, Congress authorized the Attorney General to specify, by regulation, chemicals as list I chemicals.²¹ This authority has been delegated to the Administrator of DEA,²² and DEA regulations address how DEA may add and regulate a chemical as a list I chemical, including the importation of that chemical.²³ Listing a chemical in the CSA does not regulate foreign commerce.

Comment: The commenter claims that DEA's regulatory strategy is ineffective and counterproductive.

DEA Response: DEA is concerned with the abuse of illicitly manufactured fentanyl in the United States and believes this rule will help control the illicit manufacture of fentanyl.

Comment: Finally, the commenter claims that DEA's history undermines trust in its motives. Specifically, the commenter stated that DEA has a long and documented history of misconduct that calls into question its judgment and motives.

²¹ 21 U.S.C. 802(34).

²² 28 CFR 0.100(b).

²³ See, e.g., 21 CFR 1310.02(c) (adding a chemical); 21 CFR 1313.12-.17 (importation of listed chemicals).

DEA Response: The comment about having trust in DEA's motives is outside the scope of this rule.

Chemical Mixtures of Propionyl Chloride

Under the rulemaking, chemical mixtures containing propionyl chloride are not exempt from regulatory requirements at any concentration, unless an application for exemption of a chemical mixture is submitted by a propionyl chloride manufacturer and the application is reviewed and accepted by DEA under 21 CFR 1310.13. The control of chemical mixtures containing any amount of propionyl chloride is necessary to prevent the extraction, isolation, and use of propionyl chloride in the illicit manufacture of fentanyl. This rule modifies the Table of Concentration Limits in 21 CFR 1310.12(c) to reflect the fact that chemical mixtures containing any amount of propionyl chloride are subject to the CSA chemical control provisions.

Application Process for Exemption of Chemical Mixtures

DEA has implemented an application process to exempt mixtures from the requirements of the CSA and its implementing regulations.²⁴ 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

This final rule subjects propionyl chloride to all the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of list I chemicals. Upon the effective date of this rule, persons

²⁴ 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").

handling propionyl chloride, including regulated chemical mixtures containing propionyl chloride, will be required to comply with list I chemical regulations, including the following:

1. *Registration.* Any person who manufactures, distributes, imports, or exports propionyl chloride, including chemical mixtures containing propionyl chloride, or proposes to engage in the manufacture, distribution, importation, or exportation of propionyl chloride, including chemical mixtures containing propionyl chloride, must obtain a registration pursuant to 21 U.S.C. 822, 823, 957, and 958. Regulations describing registration for list I chemical handlers are set forth in 21 CFR part 1309. DEA regulations require separate registrations for manufacturing, distributing, importing, and exporting of list I chemicals.²⁵ Further, a separate registration is required for each principal place of business at one general physical location where list I chemicals are manufactured, distributed, imported, or exported by a person.²⁶

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. Under DEA implementing regulations, the warehouse in question must receive the list I chemical from a DEA registrant and shall only distribute the list I chemical back to the DEA registrant and registered location from which it was received. A warehouse that distributes list I chemicals to persons other than the registrant and registered location from which they were obtained is conducting distribution activities and is required to register as such.²⁷

Upon the effective date of this final rule, any person manufacturing, distributing, importing, or exporting propionyl chloride or a chemical mixture containing propionyl chloride will 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

²⁵ 21 CFR 1309.21.

²⁶ 21 U.S.C. 822(e)(1) and 21 CFR 1309.23(a).

²⁷ 21 U.S.C. 822(a)(1).

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 propionyl chloride or a chemical mixture containing propionyl chloride, DEA is establishing in 21 CFR 1310.09, a temporary exemption from the registration requirement for persons desiring to engage in activities with propionyl chloride or a chemical mixture containing propionyl chloride, provided that DEA receives a properly completed application for registration or application for exemption of a chemical mixture under 21 CFR 1310.13 on or before the effective date of this final rule. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration or application for exemption of a chemical mixture.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, will be effective on the effective date of the final rule. 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 propionyl chloride, nor does it supersede State or local laws or regulations. All handlers of propionyl chloride must comply with applicable State and local requirements in addition to the CSA regulatory controls.

2. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to propionyl chloride pursuant to 21 U.S.C. 830 and in accordance with 21 CFR 1310.04 and 1310.05. Pursuant to 21 CFR 1310.04, a record must be kept 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 manufacturing, inventory, and use data on an annual basis. Existing standard industry reports containing the

required information are acceptable, provided the information is separate or readily retrievable from the report.²⁸

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 a 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.²⁹

3. *Importation and Exportation.* All importation and exportation of propionyl chloride or a chemical mixture containing propionyl chloride 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 of list I chemicals in accordance with 21 CFR 1309.71–1309.73.

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

²⁸ 21 CFR 1310.05(d).

²⁹ 21 U.S.C. 830(b) and 21 CFR 1310.05(a) and (b).

6. *Liability.* Any activity involving propionyl chloride 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

This final rule has been drafted and reviewed in accordance with Executive Order (E.O.) 12866, “Regulatory Planning and Review,” section 1(b), Principles of Regulation and E.O. 13563, “Improving Regulation and Regulatory Review,” section 1(b), General Principles of Regulation. DEA scheduling actions are not subject to either E.O. 14192, Unleashing Prosperity Through Deregulation, or E.O. 14294, Fighting Overcriminalization in Federal Regulations.

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 a 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.

DEA finds that propionyl chloride is used in the illicit manufacture of the controlled substances of fentanyl, fentanyl analogues, and fentanyl-related substances, and is important to the manufacture of these substances. The replacement chemical for propionyl chloride in the respective pathways is already a list I chemical. This final rule subjects handlers of propionyl chloride to the chemical regulatory provisions of the CSA and its implementing

regulations. This final rule does not establish a threshold for domestic and international transactions of propionyl chloride. As such, all transactions of propionyl chloride, regardless of size, shall be regulated. In addition, chemical mixtures containing propionyl chloride are not exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of propionyl chloride shall be regulated pursuant to the CSA. Propionyl chloride will be subject to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of list I chemicals.

DEA evaluated the cost of this final rule. Due to many unknowns, DEA is unable to provide an estimated cost of this final rule; however, based on DEA's analysis, the Office of Information and Regulatory Affairs has determined that this final rule is not economically significant under section 3(f)(1) of E.O. 12866.

Costs

Propionyl chloride is used for the legitimate manufacturing of pharmaceutical fentanyl as well as clandestinely synthesized illicit fentanyl. DEA has searched information in the public domain for legitimate uses of propionyl chloride and has documented that propionyl chloride may be used as an intermediary chemical in several industries, including the production of fentanyl. However, this rule would only impose regulations on those who manufacture, distribute, import, or export propionyl chloride and not end users who are using the chemical as an intermediate.

The primary costs associated with this rule would be the annual registration fee for list I chemicals (\$3,699 for manufacturers and \$1,850 for distributors, importers, and exporters). DEA has identified 20 domestic distributors of propionyl chloride. Three are already registered to handle list I chemicals, and this rule will not have impacts on their operations. The remaining distributors will need to register with DEA and employ security and handling processes to continue supplying propionyl chloride. For the nonregistered

suppliers, it is difficult to estimate the amount of propionyl chloride that they distribute. It is also common for these chemical distributors to have items in their catalog while not actually having any material level of sales. Hence, DEA expects the quantities of propionyl chloride distributed by nonregistered distributors to be much smaller compared to the registered distributors. These distributors are expected to choose the least cost option, and stop selling propionyl chloride, rather than incur the registration cost. DEA expects that the cost of foregone sales will be small; and thus, the cost of this rule is minimal. DEA requested public comments regarding this estimate, however no public comment was received during the notice and comment period regarding the costs to industry.

Benefits

Controlling propionyl chloride is expected to prevent, curtail, and limit the unlawful manufacture and distribution of the controlled substance, fentanyl, as well as fentanyl analogues and fentanyl-related substances. As a list I chemical, handling of propionyl chloride requires registration with DEA and various controls and monitoring as required by the CSA. This rule is also expected to assist in preventing the possible theft or diversion of propionyl chloride from any legitimate firms. DEA also believes control is necessary to prevent unscrupulous chemists from synthesizing propionyl chloride and selling it (as an unregulated material) through the internet and other channels, to individuals who may wish to acquire unregulated intermediary chemicals for the purpose of illicitly manufacturing fentanyl, fentanyl analogues, and fentanyl-related substances.

In summary, DEA conducted a qualitative analysis of this final rule. DEA believes any manufacturer or distributor that uses propionyl chloride for legitimate pharmaceutical fentanyl production already would be registered with DEA and have all security and other handling processes in place, such that this regulation would result in minimal cost to those entities. Therefore, any potential cost as a result of this regulation is minimal.

This rulemaking meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 Civil Justice Reform 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 final 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 rulemaking does not have tribal implications warranting the application of E.O. 13175. This final rule 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, 5 U.S.C. 601-612, 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, with this rulemaking, propionyl chloride and chemical mixtures containing propionyl chloride will be subject to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of list I chemicals. This rulemaking will affect all business activities that handle propionyl chloride including manufacturers, distributors, importers, and exporters. DEA identified 20 domestic suppliers, 17 (85 percent) of which are not registered with DEA to handle list I chemicals. All non-registered entities will be affected by this rule

and are small entities based on Small Business Administration classification for Other Chemical and Allied Products Merchant Wholesalers (NAICS classification code 424690).³⁰

There are 8,804 small entities under 424690 Other Chemical and Allied Products Merchant Wholesalers.³¹ The number of small entities affected by this final rule is 0.19 percent of all the small businesses in this industry.³² Based on these factors, DEA projects that this rule 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 “Regulatory Flexibility Act” 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 for inflation) in any one year. . . .” Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.³³ This action would not impose recordkeeping or reporting requirements on state or local governments, individuals, businesses, or organizations. However, this rule requires compliance with the following existing OMB collections: 1117-0003, 1117-0004, 1117-0006, 1117-0008, 1117-0009, 1117-0010, 1117-0012, 1117-0014, 1117-0021, 1117-0023, 1117-0029, and 1117-0056. An agency may not

³⁰ U.S. Small Business Administration, Table of size standards, Version March 2023, Effective: March 17, 2023, <https://www.sba.gov/sites/sbagov/files/2023->

³¹ 2021 SUSB Annual Data Tables by Establishment Industry, <https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html>, accessed: 1/9/2024

³² Assuming all of the 17 non-registered suppliers are small businesses, the percent of small businesses affected by this rule is $17/8,804 = 0.19\%$

³³ 44 U.S.C. 3501 through 3521.

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.

List of Subjects in 21 CFR part 1310

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

For the reasons set out above, DEA amends 21 CFR part 1310 as follows:

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

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

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

2. In § 1310.02, add paragraph (a)(41) to read as follows:

§ 1310.02 Substances covered.

* * * * *
(a) * * *

* * * * *	
(41) Propionyl chloride	8337

* * * * *

3. In § 1310.04:

- a. Redesignate paragraphs (g)(1)(xix) and (g)(1)(xx) as paragraphs (g)(1)(xx) and (g)(1)(xxi), respectively; and
- b. Add new paragraph (g)(1)(xix).

The addition reads as follows:

§ 1310.04 Maintenance of records.

* * * * *

(g) * * *

(1) * * *

(xix) Propionyl chloride

* * * * *

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

§ 1310.09 Temporary exemption from registration.

* * * * *

(t)(1) Each person required under 21 U.S.C. 822 and 21 U.S.C. 957 to obtain a registration to manufacture, distribute, import, or export propionyl chloride, including regulated chemical mixtures pursuant to § 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 propionyl chloride pursuant to § 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 propionyl chloride whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will 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, table in paragraph (c) is amended by adding in alphabetical order an entry for “Propionyl chloride” to read as follows:

§ 1310.12 Exempt chemical mixtures.

* * * * *

(c) * * *

TABLE OF CONCENTRATION LIMITS

	DEA chemical code number	Concentration	Special conditions
List I Chemicals			

Propionyl chloride	8337	Not exempt at any concentration	Chemical mixtures containing any amount of propionyl chloride are not exempt.

* * * * *

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on February 25, 2026, by Administrator Terrance C. 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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