DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–631]

Schedules of Controlled Substances: Temporary Placement of Isotonitazene in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Proposed amendment; notice of intent.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is issuing this notice of intent to publish a temporary order to schedule *N,N*-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (commonly known as isotonitazene), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I of the Controlled Substances Act. When it is issued, the temporary scheduling order will impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle isotonitazene.

DATES: June 18, 2020.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION: This document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary scheduling order (in the form of a temporary amendment) to add isotonitazene to schedule I under the Controlled Substances Act (CSA).[1] The temporary scheduling order will be published in the **Federal Register** on or after July 20, 2020.

Legal Authority

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b), if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of DEA (Administrator). 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA.[2] The Acting Administrator transmitted notice of his intent to place isotonitazene in schedule I on a temporary basis to the Assistant Secretary for Health of HHS (Assistant Secretary) by letter dated March 2, 2020. The Assistant Secretary responded to this notice by letter dated March 31, 2020, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications (INDs) or approved new drug applications (NDAs) for isotonitazene. The Assistant Secretary also stated that HHS had no objection to the temporary placement of isotonitazene in schedule I of the CSA. Isotonitazene is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for isotonitazene under section 505 of the FDCA, 21 U.S.C. 355.

To find that placing a substance temporarily in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

Isotonitazene

The availability of synthetic opioids in the illicit drug market continues to pose an imminent hazard to the public safety. Adverse health effects associated with the abuse of synthetic opioids and the continued evolution and increased popularity of these substances have been a serious concern in recent years. As the United States continues to experience an unprecedented epidemic of opioid misuse and abuse, the presence of new synthetic opioids with no approved medical use exacerbates the epidemic. The trafficking and abuse of new synthetic opioids are deadly new trends.

The identification of isotonitazene in the illicit drug market has been reported in Canada, Estonia, Germany, Latvia, Sweden, and the United States (see Factor 4 below). Data obtained from preclinical pharmacology studies show that isotonitazene has the pharmacological profile similar to that of the potent synthetic opioid etonitazene, a schedule I controlled substance. Because of the pharmacological similarities of isotonitazene to etonitazene, the use of isotonitazene presents a high risk of abuse and may negatively affect users and communities. The abuse of isotonitazene has been associated with at least 19 fatalities in the United States (see Factor 5 below). The positive identification of this substance in post-mortem cases is a serious concern for public safety. Thus, isotonitazene poses an imminent hazard to public safety.

Available data and information for isotonitazene, as summarized below, indicates that this substance has a high potential for abuse, no currently accepted medical use in treatment in the

[1] Though DEA has used the term ''final order'' with respect to temporary scheduling orders in the past, this notice of intent adheres to the statutory language of 21 U.S.C. 811(h), which refers to a ''temporary scheduling order.'' No substantive change is intended.

[2] The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

United States, and a lack of accepted safety for use under medical supervision. DEA's three-factor analysis is available in its entirety under ''Supporting and Related Material'' of the public docket for this action at *www.regulations.gov* under Docket Number DEA–631.

Factor 4. History and Current Pattern of Abuse

The chemical syntheses of isotonitazene (a benzimidazole derivative) and other benzimidazole derivatives (including schedule I substances such as synthetic opioids etonitazene and clonitazene) were first reported in the scientific literature in 1957. Isotonitazene is not an approved pharmaceutical product and is not approved for medical use anywhere in the world. As discussed in the background section, the Assistant Secretary stated in a March 31, 2020 letter to DEA that there are no INDs or FDA-approved NDAs for isotonitazene in the United States. Hence, DEA notes there is no legitimate channel for isotonitazene as a marketed drug product.

Since 2014, numerous synthetic opioids structurally related to fentanyl and several opioids from other structural classes have begun to emerge in the illicit drug market as evidenced by the identification of these drugs in forensic drug exhibits and toxicology samples. Beginning in April 2019, isotonitazene emerged on the illicit synthetic drug market in the United States as evidenced by its identification in drug seizures and in biological samples collected and submitted to National Medical Services (NMS) Laboratory [3] in August 2019. In August 2019, isotonitazene was first reported in a drug case in Belgium and toxicology casework in Canada (toxicological sample was collected in March 2019). In the United States, the Center for Forensic Science Research and Education (under the novel psychoactive substances discovery program) first reported isotonitazene in November 2019.

According to a report by the European Monitoring Center for Drugs and Drug addiction and Europol,[4] between April 2019 and January 2020, four member states (Estonia, Latvia, Germany, and Sweden) have reported 24 isotonitazene cases involving 109.6 g of powder (22 cases) and 4.5 g of liquid (two cases). Isotonitazene has been encountered by US law enforcement primarily in powder form. In March 2020, Canada law enforcement also encountered isotonitazene in tablet form as a white triangular tablet with 'M' logo on one side and '8' logo on the other side and as a blue tablet in Dilaudid counterfeit pills. Identification of isotonitazene in counterfeit pills is deeply concerning because the identity, purity, and quantity of isotonitazene in this formulation are uncertain, thus presenting additional safety concerns for unsuspecting users.

In the United States, isotonitazene has been identified as a single substance or in combination with other substances. In April 2019, the United States Customs and Border Protection (CBP) seized 1.6 grams of isotonitazene in California. In addition, Wisconsin State Crime Laboratories identified isotonitazene mixed with heroin and bromazolam, a nonscheduled benzodiazepine, in seized powder. Further, isotonitazene was identified in a substance obtained from the scene of a death investigation case in Iowa. Evidence suggests that individuals are using isotonitazene as a replacement to heroin or other opioids, either knowingly or unknowingly.

Factor 5. Scope, Duration, and Significance of Abuse

Isotonitazene, similar to etonitazene (schedule I), has been described as a potent synthetic opioid and evidence suggests it is being abused for its opioidergic effects (see Factor 6). The abuse of isotonitazene, similar to other synthetic opioids, has resulted in adverse health effects. Isotonitazene has been positively identified in 18 death investigation cases spanning between August 2019 and January 2020. These reports were from four states—Illinois (9), Indiana (7), Minnesota (1), and Wisconsin (1). Most (n = 12) of the decedents were male. The ages ranged from 24 to 66 years old with an average age of 41. Other substances identified in postmortem blood specimens obtained from these decedents include etizolam (6); flualprazolam, a nonscheduled benzodiazepine (7); fentanyl (6); heroin (3); tramadol, a schedule IV substance (2); and U–47700, a schedule I substance (1). The average concentration of isotonitazene in these biological samples (blood) was 2.2 ± 2.1 nanogram/milliliter (ng/ml) (range 0.4 to 9.5 ng/ml). Isotonitazene was detected as the only opioid in 50 percent (n = 9) of the specimens for these decedents. DEA is aware of another postmortem case in Pennsylvania where isotonitazene was identified in a biological sample. In total, isotonitazene has been positively identified in 19 postmortem cases.

Law enforcement data indicate that isotonitazene has appeared in the United States' illicit drug market. According to the National Forensic Laboratory Information System (NFLIS) [5] database, which collects drug identification results from drug cases submitted to and analyzed by Federal, State and local forensic laboratories, there have been eight encounters of isotonitazene in the United States (queried March 5, 2020). These eight encounters were in 2019 and in two states, Tennessee (7) and California (1). One of these encounters consisted of 1.6 grams of isotonitazene seized by the CBP in California in April 2019.

The population likely to abuse isotonitazene appears to be the same as those abusing prescription opioid analgesics, heroin, tramadol, fentanyl, and other synthetic opioid substances. This is evidenced by the types of other drugs co-identified in isotonitazene fatal overdose cases. Because abusers of isotonitazene are likely to obtain it through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to the end user. The misuse and abuse of opioids have been demonstrated and are well characterized. According to the most recent data from the National Survey on Drug Use and Health (NSDUH),[6] as of 2018, an estimated 10.3

[3] NMS Labs, in collaboration with the Center for Forensic Science Research and Education at the Fredric Rieders Family Foundation and the Organized Crime Drug Enforcement Task Force at the U.S. Department of Justice, has received funding from the Centers for Disease Control and Prevention to develop systems for the early identification and notification of novel psychoactive substances in the drug supply within the United States.

[4] European Monitoring Centre for Drugs and Drug Addiction and Europol (2020), EMCDDA initial report on the new psychoactive substance N,N-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1H-benzimidazole-1-ethanamine (isotonitazene). In accordance with Article 5b of Regulation (EC) No. 1920/2006 (as amended), Publications Office of the European Union, Luxembourg.

[5] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive information system that includes data from forensic laboratories that handle the nation's drug analysis cases. NFLIS-Drug participation rate, defined as the percentage of the national drug caseload represented by laboratories that have joined NFLIS, is currently 98.5 percent. NFLIS includes drug chemistry results from completed analyses only. While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332, Dec. 12, 2011. NFLIS data was queried on March 5, 2020.

[6] The National Survey on Drug Use and Health (NSDUH), formerly known as the National Household Survey on Drug Abuse (NHSDA), is conducted annually by HHS' Substance Abuse and Mental Health Services Administration (SAMHSA). It is the primary source of estimates of the prevalence and incidence of nonmedical use of

million people aged 12 years or older had misused opioids in the past year, including 9.9 million prescription pain reliever misusers and 808,000 heroin users. In 2018, an estimated 2.0 million people had an opioid use disorder which included 1.7 million people with a prescription pain reliever use disorder and 0.5 million people with heroin use disorder. This population abusing opioids is likely to be at risk of abusing isotonitazene. Individuals who initiate (*i.e.,* use a drug for the first time) use of isotonitazene are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (*e.g.,* fentanyl, morphine, etc.). Law enforcement and toxicology reports demonstrate that isotonitazene is being illicitly distributed and abused.

Factor 6. What, if Any, Risk There Is to the Public Health

The increase in opioid overdose deaths in the United States has been exacerbated recently by the availability of potent synthetic opioids in the illicit drug market. Data obtained from pre-clinical studies demonstrate that isotonitazene exhibits a pharmacological profile similar to that of etonitazene and other mu-opioid receptor agonists. In an *in vivo* (in mice) study, isotonitazene was 500 times more potent than morphine as an analgesic in a tail-flick assay. The tail-flick assay is useful in evaluating antinociceptive effect. Data from *in vitro* studies showed that isotonitazene activated the mu-opioid receptor and acted as a mu-opioid receptor agonist. Isotonitazene, similar to hydromorphone and fentanyl, activated the mu-opioid receptor and acted as an agonist via interaction at the mu-opioid receptor with β-arrestin-2, a regulatory protein, in a live cell-based receptor assay. Naloxone, an opioid receptor antagonist, blocked isotonitazene's activation of the mu-opioid receptor. Substances that act as an agonist at the mu-opioid receptors have a high potential for addiction and can induce dose-dependent respiratory depression.

As with any mu-opioid receptor agonist, the potential health and safety risks for users are high. The public health risks attendant to the abuse of heroin and other mu-opioid receptor agonists are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses. According to the Centers for Disease Control and Prevention (CDC), opioids, mainly synthetic opioids other than methadone, are predominantly responsible for drug overdose deaths in recent years. A CDC report shows that from 2013 to 2018,[7] opioid-related overdose deaths in the United States increased from 25,052 to 46,802. Of the drug overdose death data for 2018, opioids were involved in about 69.5 percent of all drug-involved overdose deaths.

Isotonitazene has been co-identified with other substances in 18 postmortem cases and DEA is aware of an additional death case that occurred in January 2020 involving isotonitazene in the United States. These deaths associated with isotonitazene occurred in five states-Illinois (9), Indiana (7), Minnesota (1), Pennsylvania (1), and Wisconsin (1). Information gathered from case histories and autopsy findings shows that isotonitazene use is similar to that of classic opioid agonists. Evidence obtained from reported cases of death scenes suggests that isotonitazene, similar to heroin, can be used intravenously.[8]

The introduction of potent synthetic opioids such as isotonitazene into the illicit market is a portal to problematic opioid use for those seeking these powerful opioids. As documented by a published toxicology report, poly-substance abuse remains common in fatalities associated with the abuse of isotonitazene.[9]

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of isotonitazene pose an imminent hazard to the public safety. DEA is not aware of any currently accepted medical uses for isotonitazene in the United States. A substance meeting the statutory requirements for temporary scheduling, found in 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for isotonitazene indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by 21 U.S.C. 811(h)(4), the Acting Administrator, through a letter dated March 2, 2020, notified the Assistant Secretary for Health of DEA's intention to temporarily place isotonitazene in schedule I.

Conclusion

This notice of intent provides the 30-day notice pursuant to 21 U.S.C. 811(h)(1) of DEA's intent to issue a temporary scheduling order. In accordance with 21 U.S.C. 811(h)(1) and (3), the Acting Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule isotonitazene in schedule I of the CSA, and finds that placement of this substance in schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety.

The temporary placement of isotonitazene in schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before July 20, 2020. Because the Acting Administrator hereby finds that it is necessary to temporarily place isotonitazene in schedule I to avoid an imminent hazard to the public safety, the temporary order scheduling this substance will be effective on the date the order is published in the **Federal Register,** and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Acting Administrator to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this document. Upon publication of the temporary order, isotonitazene will then be subject to the CSA's schedule I

pharmaceutical drugs, illicit drugs, alcohol, and tobacco use in the United States. The survey is based on a nationally representative sample of the civilian, non-institutionalized population 12 years of age and older. The survey excludes homeless people who do not use shelters, active military personnel, and residents of institutional group quarters such as jails and hospitals. The NSDUH provides yearly national and state level estimates of drug abuse, and includes prevalence estimates by lifetime (*i.e.,* ever used), past year, and past month abuse or dependence. The 2018 NSDUH annual report is available at *https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf* (last accessed April 9, 2020).

[7] CDC—National Center for Health Statistics (NCHS), National Vital Statistics System, Mortality. NCHS Data Brief, Number 356, January 2020.

[8] Krotulski AJ, Papsun DM, Kacinko SL, and Logan BK (2020). Isotonitazene Quantitation and Metabolite Discovery in Authentic Forensic Casework. *Journal of Analytical Toxicology.* [Epub ahead of print].

[9] *Id.*

regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession.

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Analyses

21 U.S.C. 811(h) provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from: (1) The publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as 21 U.S.C. 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, including the requirement of a publication in the **Federal Register** of a notice of intent, the notice-and-comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this Notice of Intent. The APA expressly differentiates between an order and a rule, as it defines an ''order'' to mean a ''final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making*.'' 5 U.S.C. 551(6) (emphasis added). The specific language chosen by Congress indicates an intention for DEA to proceed through the issuance of an *order* instead of proceeding by rulemaking. Given that Congress specifically requires the Attorney General to follow rulemaking procedures for *other* kinds of scheduling actions, *see* 21 U.S.C. 811(a), it is noteworthy that, in 21 U.S.C. 811(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Acting Administrator finds that there is good cause to forgo the notice-and-comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice-and-comment requirements of section 553 of the APA, DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Acting Administrator took into consideration comments submitted by the Assistant Secretary in response to the notice that DEA transmitted to the Assistant Secretary pursuant to such subsection.

Further, DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

In accordance with the principles of Executive Orders 12866, 13563, and 13771, this action is not a significant regulatory action. Executive Order 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). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. Executive Order 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 Executive Order. Because this is not a rulemaking action, this is not a significant regulatory action as defined in Section 3(f) of Executive Order 12866. In addition, this action does not meet the definition of an Executive Order 13771 regulatory action, and the repeal and cost offset requirements of Executive Order 13771 have not been triggered.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism), it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. In § 1308.11, add paragraph (h)(48) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(48) *N,N*-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: Isotonitazene)	9614

* * * * *

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–12304 Filed 6–17–20; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2020–0048; FRL–10010–93–Region 1]

Air Plan Approval; Rhode Island; Reasonably Available Control Technology for the 2008 and 2015 Ozone Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing approval of a State Implementation Plan (SIP) revision submitted by the State of Rhode Island. The SIP revision consists of a demonstration that Rhode Island meets the requirements of reasonably available control technology (RACT) for the two precursors for ground-level ozone, oxides of nitrogen (NO_X) and volatile organic compounds (VOCs), set forth by the Clean Air Act (CAA or Act) with respect to the 2008 and 2015 ozone National Ambient Air Quality Standards (NAAQSs or standards). Additionally, we are proposing approval of specific regulations that implement the RACT requirements by limiting air emissions of NO_X and VOC pollutants from sources within the State. This action is being taken in accordance with the Clean Air Act.

DATES: Written comments must be received on or before July 20, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2020–0048 at *https://www.regulations.gov,* or via email to *mackintosh.david@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays and facility closures due to COVID–19.

FOR FURTHER INFORMATION CONTACT: David L. Mackintosh, Air Quality Branch, U.S. Environmental Protection Agency, EPA Region 1, 5 Post Office Square—Suite 100, (Mail Code 05–2), Boston, MA 02109–3912, tel. 617–918–1584, email *Mackintosh.David@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

Table of Contents

I. Background

Rhode Island is part of the Ozone Transport Region (OTR) under Section 184(a) of the CAA. Sections 182(b)(2), 182(f) and 184 of the CAA require states with ozone nonattainment areas that are classified as moderate or above, as well as areas in the OTR, to submit a SIP revision requiring the implementation of VOC RACT for sources covered by a control techniques guideline (CTG) and for all major sources of VOC and NO_X. A CTG is a document issued by EPA which establishes a ''presumptive norm'' for RACT for a specific VOC source category. RACT is defined as the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility.[1] The CTGs usually identify a particular control level which EPA recommends as being RACT. States are required to address RACT for the source categories covered by CTGs through adoption of rules as part of the SIP.

On October 5, 2006 (71 FR 58745), EPA issued four new CTGs: Industrial Cleaning Solvents; Offset Lithographic Printing and Letterpress Printing; Flexible Package Printing; and Flat Wood Paneling Coatings, and applicable areas were required to address them by October 5, 2007. On October 9, 2007 (72 FR 57215), EPA issued three more CTGs: Paper, Film, and Foil Coatings; Large Appliance Coatings; and Metal Furniture Coatings, and applicable areas were required to address them by October 9, 2008. On October 7, 2008 (73 FR 58841), EPA issued an additional four CTGs: Miscellaneous Metal and Plastic Parts Coatings; Fiberglass Boat Manufacturing Materials; Miscellaneous Industrial Adhesives; and Automobile and Light-Duty Truck Assembly Coatings. Applicable areas were required to address these CTGs by October 7, 2009. Lastly, on Oct 27, 2016 (81 FR 74798), EPA issued a new CTG for the Oil and Natural Gas Industry, and applicable areas were required to address it by October 27, 2018.

On March 27, 2008 (73 FR 16436), EPA revised the health-based NAAQS for ozone to 0.075 parts per million (ppm), averaged over an 8-hour timeframe. EPA determined that the revised 8-hour standard would be more protective of human health, especially with regard to children and adults who are active outdoors and individuals with a pre-existing respiratory disease such as asthma.

On March 6, 2015 (80 FR 12264), EPA published a final rule outlining the obligations for areas in nonattainment with the 2008 ozone standard, as well as obligations for areas in the OTR. This rule, referred to as the ''2008 Ozone Implementation Rule,'' contains a description of EPA's expectations for states with RACT obligations, and required states in the OTR to certify RACT requirements by July 20, 2014. The 2008 Ozone Implementation Rule gives states several options for meeting RACT requirements for the 2008 ozone

[1] See Memorandum from Roger Strelow, Assistant Administrator for Air and Waste Management, U.S. EPA, to Regional Administrators, U.S. EPA, ''Guidance for Determining Acceptability of SIP Regulations in Non-Attainment Areas'' (Dec. 9, 1976); see also 44 FR 53761, 53762 (September 17, 1979).