



United Nations
Office on Drugs and Crime



NATIONAL SECRETARIAT FOR
DRUG POLICIES AND
ASSET MANAGEMENT

MINISTRY OF
JUSTICE AND
PUBLIC SECURITY



EXECUTIVE SUMMARY

NITAZENES

CHARACTERIZATION AND PRESENCE IN BRAZIL



Idealization

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The valuable comments and contributions of João Rodrigues, Scientific Affairs Officer, Laboratory and Scientific Services, UNODC, to the preparation of this report are gratefully acknowledged.

Suggested citation:

CDESC, Nitazenes: Characterization and presence in Brazil. Brasília: MJSP; PNUD; UNODC, 2025.

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Esplanada dos Ministérios, Bloco T, Palácio da Justiça - Edifício Sede. Brasília - DF. CEP: 70064-900.

Digital version available at: www.cdasc.org.br/publicacoes

362.293
N728

Nitazenes – executive summary : characterization and presence in Brazil / elaboración Gabriela Hamú Giudice ... [et al.] ; coordenação Bárbara Diniz Caldeira, Barbara Caballero. -- Brasília : Center for Studies on Drugs and Community Social Development (CDESC), United Nations Office on Drugs and Crime (UNODC), United Nations Development Programme (UNDP), Ministry of Justice and Public Security (MJSP), 2025.
16 p. : il. color.

Trabalho em parceria da Secretaria Nacional de Políticas sobre Drogas e Gestão de Ativos do Ministério da Justiça e Segurança Pública com o Escritório das Nações Unidas sobre Drogas e Crime (UNODC), Programa das Nações Unidas para o Desenvolvimento (PNUD).

Digital version available at: www.cdasc.org.br/publicacoes

ISBN digital 978-85-5506-223-0

1. Droga ilícita, mercado, Brasil - 2. Droga, terminologia, sumário – I. Giudice, Gabriela Hamú. II. Caldeira, Bárbara Diniz (coord.). III. Caballero, Barbara (coord.). IV. Centro de Estudos sobre Drogas e Desenvolvimento Social Comunitário (CDESC). V. Escritório das Nações Unidas sobre Drogas e Crime (UNODC). VI. Programa das Nações Unidas para o Desenvolvimento (PNUD). VII. Brasil. Ministério da Justiça e Segurança Pública. VIII. Título.

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SUMMARY

INTRODUCTION	5
METHODOLOGY	6
WHAT ARE NITAZENES?	7
GLOBAL DATA.....	8
NATIONAL DATA.....	10
MAIN CONCLUSIONS.....	14
BIBLIOGRAPHICAL REFERENCES	15

INTRODUCTION

New Synthetic Opioids (NSO), a kind of New Psychoactive Substance (NPS), raise concern due to their high potency and risks associated with their use. Many such opioids are not yet controlled nationally or internationally and may be present in illegal drugs, often without knowledge from drug consumers. Among opioids, nitazenes have risen to prominence globally due to the recent increase in police seizures and the continuous emergence of new chemical compounds.

Nitazenes are a group of 2-benzylbenzimidazole-derived NPS. Despite their recent emergence in drug markets, these substances were initially synthesized as opioid analgesics in the 1950s but were never commercialized due to their high potential for abuse, among other factors. In this group, eight compounds are currently internationally controlled under the United Nations Single Convention on Narcotic Drugs of 1961: etonitazene and clonitazene, controlled since the Convention's original publication; butonitazene, added in 2024; etazene, etonitazepyne and protonitazene, added in 2023; metonitazene, in 2022; and isotonitazene included in 2021.

This Executive Summary presents the main findings of the study "Nitazenes: characterization and presence in Brazil". This document provides an overview on nitazenes in an international context and then addresses the topic in the Brazilian scenario, based on a review of the current literature and on data provided by different sources. These include forensic chemistry laboratories from the Brazilian Federative Units, the National Institute of Criminalistics of the Brazilian Federal Police (INC/PF, in its Portuguese acronym), forensic toxicology laboratories from the Brazilian Federative Units, the Toxicological Information and Assistance Centers (CIA-Tox, in its Portuguese acronym) and harm reduction groups (RD, in its Portuguese acronym).

The main objective of this study is to provide reliable information and support decision-makers in formulating actions and developing evidence-based policies on prevention and risk mitigation – and as such, to ultimately limit risks and reduce hazards associated with the use of nitazenes.

This document was elaborated by the Center for Studies on Drugs and Community Social Development (CDESC, in its Portuguese acronym), a project resulting from the partnership between the National Secretariat for Drug Policy and Asset Management of the Ministry of Justice and Public Security (SENAD/MJSP), the United Nations Development Programme (UNDP) and the United Nations Office on Drugs and Crime (UNODC). Among its areas of activity, CDESC carries out research and analysis in order to inform drug policies and supports the implementation of an Early Warning System (SAR, in its Portuguese acronym) for NPS and other emerging drug-related phenomena in Brazil. This publication also seeks to encourage the development of new studies in the area, to support the formulation of evidence-based policies and actions, and to provide relevant information that could be of interest to the general public.

As a guardian of the UN's three International Conventions on Drugs, the UNODC plays a key role in promoting coordinated global responses to challenges related to use, production and trafficking of psychoactive substances.

METHODOLOGY

The research for this publication began by reviewing articles about the topic of nitazenes and collecting relevant documents produced by international bodies, such as UNODC, World Health Organization (WHO), International Narcotics Control Board (INCB), Inter-American Drug Abuse Control Commission (CICAD) and the European Union Drug Agency (EUDA). It also included an analysis of documents from collections of relevant national agencies, such as the National Health Regulatory Agency (ANVISA, in its Portuguese acronym), the Oswaldo Cruz Foundation (FIOCRUZ, in its Portuguese acronym), the Ministry of Justice and Public Security (MJSP) and the São Paulo Technical-Scientific Police. The article "*Synthetic Illicit Opioids in Brazil: Nitazenes Arrival*", published in June 2024, by Araújo et al., in *Forensic Science International* also became a central source of information for this document. As part of its methodological strategy to gather Brazilian data on the subject, CDESC has also collected, through electronic forms, official data from forensic chemistry and forensic toxicology laboratories of the Brazilian states, as well as from the Federal Police. CIATox and harm reduction groups across Brazilian states were also consulted using the data-collection techniques¹.

The electronic forms used in the data-collection process were made available on July 23rd, 2024 and closed on August 12th, 2024. They were sent to representatives of forensic chemistry laboratories in all Brazilian Federative Units and to the Federal Police's central forensic laboratory (INC), as well as to forensic toxicology laboratories in 25 Brazilian states - excluding the Federal District (DF) and Mato Grosso do Sul (MS). Forms were also sent to 32 CIATox centers in 20 states and to 17 harm reduction groups.

In total, CDESC has received 48 responses (16 from forensic chemistry laboratories, including the Federal Police; 13 from forensic toxicology laboratories; 15 from CIATox; and 4 from RD groups).

State forensic chemistry laboratories perform the chemical analysis of substances seized by state level police forces, while the Federal Police laboratories are responsible for analyzing seized substances related to international and interstate drug trafficking or through partnerships with state laboratories. In the context of local criminal investigations, forensic toxicology laboratories analyse biological materials. CIATox centers provide toxicological assistance and seek to share information

1 All Federative Units (Brazilian states + Federal District) have at least one state laboratory for forensic chemistry. The official laboratory for forensic toxicology in the Federal District was not included in this research due to the impossibility in contacting it during the data collection process. The state of Mato Grosso do Sul (MS) does not have a state laboratory for forensic toxicology. The harm reduction groups contacted were the following: ABEPSS; Ancore; BalanCE - Risk and Harm Reduction; Coletivo Bateu - Harm Reduction Brasília; Coletivo Bem Te Vi; Coletivo Cai Junto; CoNéctar RD; NGO Arco; Coletivo Minimizes; Coletivo Lótus; Coletivo Massunim; Coletivo Oráculo; Metanoia - Harm Reduction; Coletivo Repense; Projeto ResPire; SobreViver RD; Escola Livre de Redução de Danos.

and to advise healthcare services and the general public about risks associated with chemical and biological substances, such as pesticides, toxic plants, venomous animals, drugs and medicine, or any other potentially toxic agent.

Harm reduction groups are Civil Society Organizations (CSO) that use strategies such as substance testing and information dissemination to provide care for people who use drugs.

WHAT ARE NITAZENES?

Nitazenes are a group of NPS, classified as synthetic opioids that have emerged in illicit drug markets in recent years. Despite their recent emergence, nitazenes were initially synthesized in the 1950s as opioid analgesics, but were never sold as commercial drugs due to their high potential for abuse, among other reasons (Pergolizzi JR, 2023). Nitazenes are derived from a 2-benzylbenzimidazole nucleus, and, as such, are highly compatible with opioid receptors in the brain, resulting in powerful analgesic and sedative effects.

Substances in this group are notable for being highly potent, sometimes as much as a hundred or a thousand times as powerful as morphine or other opioids (Papsun, Krotulski, Logan, 2022; Pergolizzi JR, 2023), which in turn increases potential risks of overdose.

Since nitazenes mimic the effects of traditional opioids, they present a high potential for addiction. Despite the toxicological properties of nitazenes not yet being widely studied, their use can cause dizziness, nausea, disorientation and convulsions, among other effects. They also present a high risk of central nervous system or respiratory depression and cardiac arrest. (CICAD, 2024; UNODC, 2024a).

Much like other opioids, nitazene-induced overdoses can be reversed by naloxone. However, more than one dose of the antidote might be required for countering overdose since nitazenes are particularly potent (CICAD, 2024). In Brazil, naloxone is scheduled under list C1 (list of other substances under special control – as mandated by Ordinance n° 344/1998 of the of the Secretariat of Health Surveillance of the Ministry of Health (Portaria SVS/MS n° 344/1998) Naloxone is available in Brazil as an injectable solution, but its distribution must be accompanied by a Specially Controlled Prescription in two copies.

Nitazenes are mostly consumed through vaping, intravenous, sublingual and intranasally via spraying or insufflation (UNODC, 2024a). These substances are commonly available in powder, tablets or liquids. They can be mixed to other non-reacting substances or other drugs, such as heroin, fentanyl, and benzodiazepines (Pergolizzi Jr, 2023), which might cause users to consume nitazenes unintentionally, and make them more vulnerable to the risks associated with these substances. (CICAD, 2024).

The following compounds belong to the general category of nitazenes:

- | | |
|--|--|
| ■ Etonitazene | ■ Etazene (or etodesnitazene) |
| ■ Clonitazene | ■ Butonitazene |
| ■ Isotonitazene | ■ Flunitazene |
| ■ Metonitazene | ■ N-desethyl Etonitazene |
| ■ Protonitazene | ■ N-pyrrolidino Metonitazene (or metonitazepyne) |
| ■ Etonitazepyne (or N-pyrrolidino Etonitazene) | ■ Metodesnitazene |

Currently, in Brazil, Ordinance nº 344/1998 (Portaria SVS/MS nº 344/1998) schedules clonitazene and etonitazene under List A1. The same regulatory instrument prohibits isotonitazene, metonitazene, etazene, etonitazepyne, protonitazene, butonitazene, N-desethyl Etonitazene, and N-pyrrolidino Metonitazene under List F1.

GLOBAL DATA

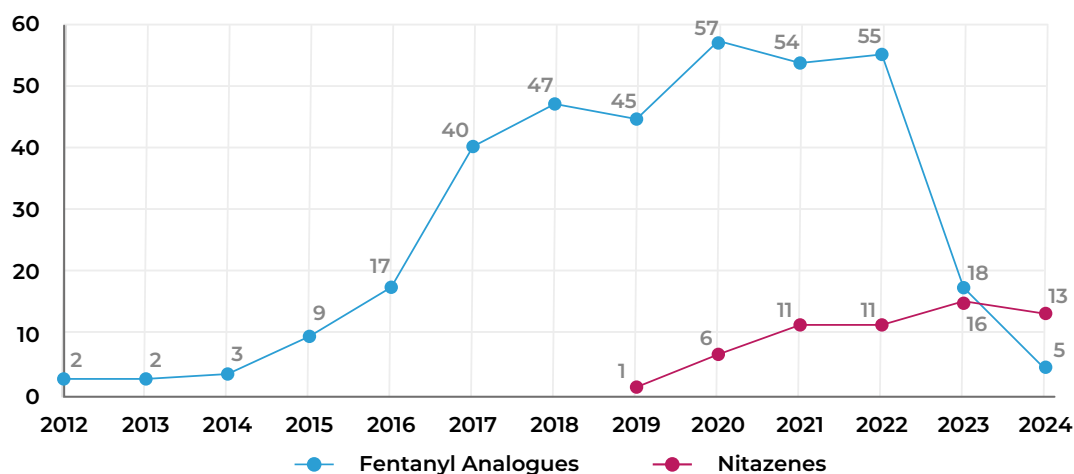
Since its publication, the 1961 UN Single Convention on Narcotic Drugs has classified etonitazene and clonitazene in Schedule I, which contains substances with restricted medical applications and a high potential for abuse (INCB, 2019). The following substances belonging to the nitazene group are currently controlled internationally: isotonitazene, since 2021; metonitazene, since 2022; protonitazene, etonitazepyne and etazene, since 2023; and butonitazene, which was added to the Convention in 2024 (INCB, 2024).

Since nitazenes have only recently emerged in illicit drug markets, comprehensive data on their distribution is not yet available (CICAD, 2024). Initial reports on etonitazene seizures and identification date back to the late 1960s (Italy), 1987 (Germany), 1998 (Russia), and 2003 (USA). One of the first isotonitazene-caused deaths was reported in Switzerland, in March of 2019. Seizures caused by the substance were also reported in Estonia, Latvia, Sweden and Germany during the same year (Ujváry et al., 2021).

In 2019, the first nitazene was reported to the UNODC Early Warning Advisory system (EWA). Since then, the countries that have reported the highest number of new nitazene molecules to the EWA, in descending order, are USA, Canada, Latvia, Estonia, the United Kingdom, Sweden, and Germany (UNODC, 2024c). 19 different nitazenes had been reported to the EWA by August 2024, and the most commonly reported compounds are isotonitazene, metonitazene, protonitazene, etonitazepyne, and etazene (UNODC, 2024b; UNODC 2024f).

The appearance of nitazenes in illicit drug markets in 2019, combined with the frequent emergence of new molecules from this category, suggests a potentially widespread – and still growing – presence of nitazenes globally. Compared to fentanyl analogues, using data from the UNODC EWA (Figure 1), a significant increase in newly reported molecules was observed between 2016 and 2017, rising from 17 different fentanyl analogues reported in 2016 to 40 in 2017. In contrast, nitazenes have shown consistent growth between 2019 and 2023 (database starts in 2019 and uses preliminary data from 2024).

Figure 1: Number of unique fentanyl analogues and unique nitazenes reported to the UNODC Early Warning Advisory System - 2012 to 2024*

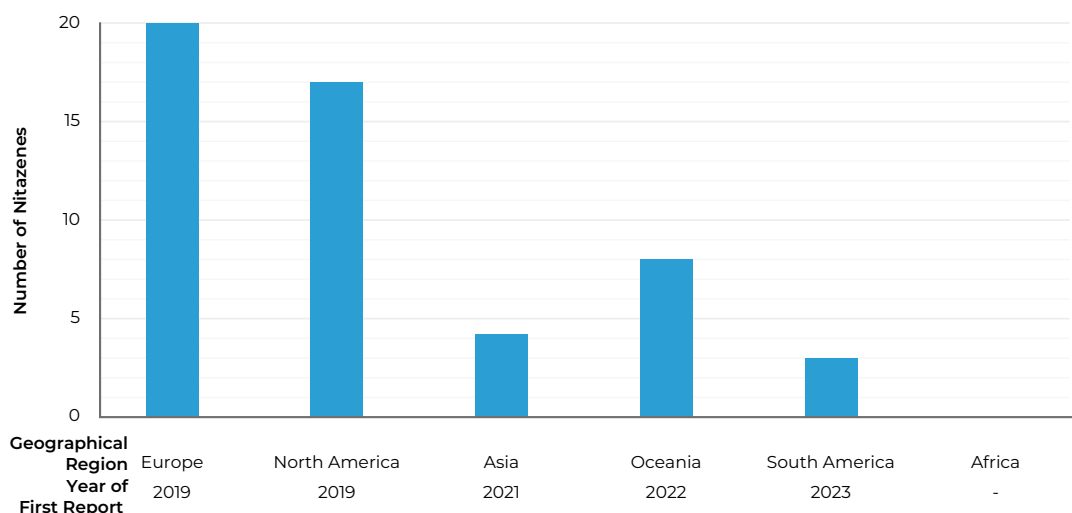


* Preliminary data for 2024 (data consulted on 26 November 2024).

It should be noted that data from previous years might be reviewed in the future.

Source: UNODC Early Warning Advisory on NPS - Summary Dashboard, 2024 (UNODC, 2024b)

Figure 2: Number of nitazenes reported to the UNODC Early Warning Advisory System, by geographical region* and year of first report - 2019 to 2024**



*Six reports on the EWA dashboard are not georeferenced. Therefore, as of the consultation date, the total number of nitazenes with an associated region is 52.

** Preliminary data for 2024 (data consulted on 26 November 2024).

It should be noted that data from previous years might be reviewed in the future.

Source: UNODC Early Warning Advisory on NPS - Summary Dashboard, 2024

Nitazenes can cause varying levels of health complications depending on the route of administration and their interaction with other substances — as is the case with any NPS (Ujváry et al., 2021). Toxicological studies and data from drug seizures point towards nitazenes being commonly combined with other psychoactive substances. As such, caring for drug users and identifying seized substances warrants careful scrutiny whenever nitazenes are present (Zawilska, 2023; Krotulski, 2021; Papsun, 2022; Pergolizzi Jr, 2023).

NATIONAL DATA

Historically, illicit opioids have circulated in Brazil in low quantities and with little diversity, and there is no evidence of an 'opioid epidemic' similar to the one observed in North America (Araújo et. al., 2024). Opioid use in Brazil is relatively low, and the associated harms are uncommon, especially in comparison to regions with high consumption levels (Maia et al., 2021). However, an increase in the presence of these substances has been observed, driven primarily by synthetic opioids (Araújo et. al., 2024). Over the last years, seizures of synthetic opioids have been getting more frequent in Brazil. (EWS, 2023). **In addition to seizures in powder form, nitazenes have also been detected in herbal fragments, usually in combination with other psychoactive substances, especially synthetic cannabinoids. This scenario suggests that nitazenes and synthetic cannabinoids are being added to a mixture of herbs, which might point towards a specific consumption pattern.**

Between July 2022 and April 2023, project INSPEQT (Investigation of New Psychoactive Substances in Chemistry and Forensic Toxicology) detected opioids in 140 samples seized by São Paulo's State Civil Police (PCSP). Nitazenes were present in 133 samples, while the others contained either morphine (2) or fentanyl (5). In all samples where morphine was detected and in three samples where fentanyl was detected, no other psychoactive substances were found. Other samples detected fentanyl in combination with THC, synthetic cannabinoids, or cocaine. Metonitazene was the most commonly detected nitazene, and 98.5% of samples were detected in the form of dried herbal fragments, which suggests consumption through inhalation (smoking) (Araújo et al., 2024). Pant materials are frequently associated with phytocannabinoids, cocaine, and synthetic cannabinoids, suggesting that users may be unknowingly consuming nitazenes.

According to the 2024 Report on New Psychoactive Substances in São Paulo, despite opioids accounting for only 7.2% of state-wide NPS seizures between July 2022 and December 2023 (NEE, 2024), these substances should still be monitored closely, as illustrated by recent news reports cases. In December 2024, for instance, the Brazilian Federal Police (PF) dismantled an illegal laboratory in Mogi das Cruzes/SP, where nitazenes were being added to herbal fragments (Polícia Federal, 2024).

According to information provided by the Center for General Police Coordination for Repression of Drugs and Criminal Factions (CGPRE/PF), the aforementioned seizure led to the seizure of 280 g of powder material and 41.3 kg of herbal fragments, both containing substances classified as nitazenes. Preliminary research has shown that 200 g of nitazene-containing powder had been added to the 41.3 kg of seized herbs.

Figure 3: Materials seized in a clandestine laboratory that was dismantled by the Federal Police in Mogi das Cruzes/SP - 2024



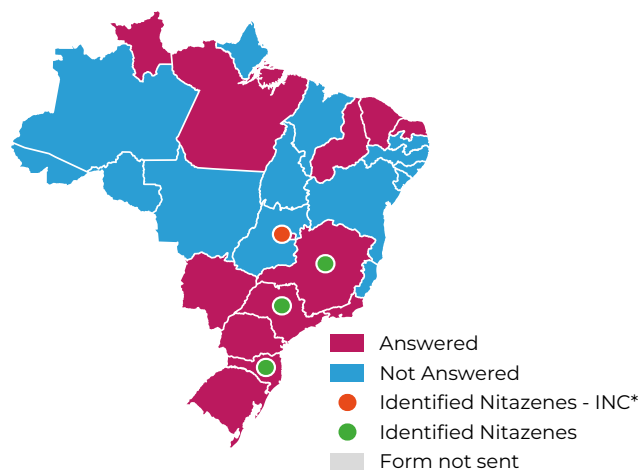
Credits: General Coordination of Police for the Repression of Drugs and Criminal Factions (CGPRE) of the Federal Police (PF).

In this context, developing a broader understanding of the bigger picture when it comes to nitazenes and their distribution in Brazil becomes a priority. **To achieve this, CDESC has developed electronic forms aimed at various institutions and key stakeholders – as has been described above (see Methodology). The objective was to gather information about nitazenes and their detection in Brazil, as well as other aspects related to these substances.**

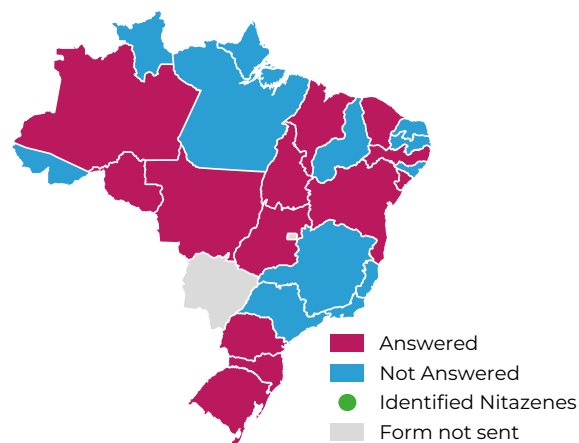
The map on figure 4 illustrates the Brazilian Federative Units that received the aforementioned online forms (highlighted in light blue), those that responded (coloured in pink) and those that identified nitazenes within their scope of operations (indicated by a green or orange circle).

Figure 4: Distribution of the Brazilian Federative Units: Reception, Responses to Forms and Identification of Nitazenes

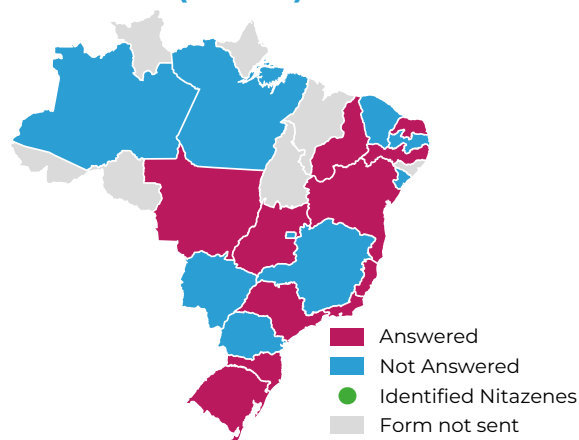
4.A - Forensic Chemistry Laboratories



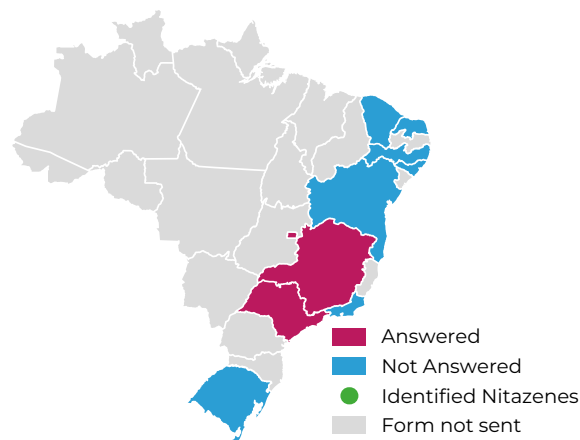
4.B - Forensic Toxicological Laboratories



4.C - Toxicological Information and Assistance Centers (CIATox)



4.D - Drug Harm Reduction Groups



* Affirmative responses of nitazene identification provided by the Federal Police's National Criminalistics Institute (INC) are represented by an orange circle in figure 4.A. Although it is indicated in the Federal District, where the Institute is located, this does not necessarily mean that the nitazene seizures occurred there, as the INC operates nationwide and analyzes materials from different states.

Source: CDESC (2024)

Responses sent from the Federal Police and forensic chemistry labs from Brazilian states have revealed that nitazenes have been seized as tablets, in herbal mixtures, and as a pure powder. **One respondent reported that the seized material was divided into doses ranging from 100 to 150 mg. The seizures carried out by the Federal Police, on the other hand, consisted of multiple 1 kg bags of pure nitazenes. In 2023, the Federal Police reported 10 kg in total seizures of substances from the nitazene group,**

an amount exceeding the total reported by the European Early Warning System, in 2022 (3 kg) (EUDA, 2024). Among nitazenes identified and reported to CDESC through the forms were metonitazene, isotonitazene, protonitazene, N-pyrrolidino metonitazene (or metonitazepyne), etonitazepyne (or N-pyrrolidino Etonitazene), and N-desethyl Etonitazene. Moreover, nitazenes have been identified in combination with synthetic cannabinoids (ADB-BUTINACA, ADB-4en-PINACA, MDMB-4en-PINACA, MDMB-BUTINACA, FLUORO-ADB, MBMB-5Br-INACA), benzodiazepines (bromazolam), stimulants (cocaine), and anaesthetics (tetracaine).

These findings are in line with data from the Narcotics Control Center in the Superintendence of Technical and Scientific Police of São Paulo, as described by Araújo et al. (2024). The study raises the hypothesis that the combination of nitazenes with synthetic cannabinoids could be intentional, an aspect that requires further investigation to elucidate its purpose.

In this context, Drug Observatories and Early Warning Systems play an increasingly relevant role, as they monitor drug tendencies and guide evidence-based public policies. Established in 2002, the Brazilian Drug Information Observatory (Obid) also collects scientific data about drugs to support prevention, care, and social reintegration initiatives surrounding drug users, while also developing interventions tailored to the sociocultural characteristics of the target populations.

Early Warning Systems (EWS) are equally fundamental when monitoring emerging drug markets, since they can assist with understanding and mitigating risks associated with NPS, such as nitazenes.

Brazil's Early Warning System, implemented experimentally in 2021 and on track to becoming fully operational since 2024, is a network aimed at detecting NPS and other emerging drug threats. The EWS also seeks to share scientific information to anticipate health and public safety risks and guide effective initiatives. Monitoring the emerging drug scenario is a crucial step in enacting preventive policies on time and protecting the general population.

Other institutions and stakeholders consulted have not reported positive responses for nitazene identification.

Notably, a forensic toxicology laboratory reported that nitazenes are not included in its scope of analysis. This highlights the fact that negative responses regarding nitazene identification do not necessarily indicate their absence in a given region, especially considering the analytical limitations present in several Brazilian states and the inherent challenges of identifying NPS.

Reinforcing this perspective, one respondent representing harm reduction groups informed that individuals assisted by the organization are aware of nitazenes and their mixture with K drugs (synthetic cannabinoids), but no cases of nitazene use were reported by those assisted at the organization.

MAIN CONCLUSIONS

Despite substances from the nitazenes group having already been detected in three Brazilian states and by the Federal Police, the responses to the online forms highlight several challenges related to nitazene identification.

Among the main obstacles mentioned by respondents are access to appropriate analytical equipment, difficulties in obtaining certified analytical standards, limited access to substance libraries, and the need for training and standardized methodologies for the identification of NPS and their metabolites. Equipment such as gas and liquid chromatographs coupled to mass spectrometers (GC/MS, LC/MS/MS, LC/QTOF/MS), infrared spectrometers (FT-IR), Raman spectrometers, and nuclear magnetic resonance (NMR) were also considered essential tools in countering these limitations.

This research highlights an urgent need for an information exchange network among the stakeholders related to the drug issue in general. Ideally, this network should be systematized to operate in a timely manner, implemented through an institutional Drug Early Warning System.

In this context, cooperation between health authorities, regulatory agencies, public safety institutions, NGOs, and civil society organizations is of utmost importance when it comes to monitoring and countering the use of nitazenes and other NPS.

Finally, scientific research on NPS and drug monitoring initiatives are equally important for better understanding these substances — and devoting energy to creating better communication systems should help improve both information-sharing and effort-coordinating initiatives surrounding these issues.

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