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## **Emerging Nicotine Pouches: Mechanisms of Action, Health Risks, and Regulatory Perspectives – A Systematic Review**

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## **Abstract**

**Background:** nicotine pouches are a growing category of smoke-free products, especially popular among adolescents. Although promoted as tobacco-free alternatives, they deliver nicotine, a highly addictive substance. Nicotine raises heart rate and blood pressure, may contribute to cardiovascular dysfunction, and affects gastrointestinal activity and immunity. Pouches enable nicotine absorption through the oral mucosa, lowering exposure to toxic byproducts, though systemic effects remain. Local use may cause mucosal irritation. Their discreet form and attractive flavors may encourage frequent use and dependence. While potentially less harmful than smoking, they are not risk-free, and evidence on their long-term effects is still limited.

**Aim:** The aim of this study was to review the current scientific literature in order to assess the impact of nicotine pouches on human health. The analysis examined available data on their systemic effects, the action of nicotine, and potential local effects in the oral cavity. Particular attention was paid to aspects related to the risk of addiction and the possible health consequences of their use.

**Material and methods:** The authors reviewed studies available in databases such as PubMed, Google Scholar, and ResearchGate. Review articles and original studies were analyzed, focusing on the health effects of nicotine pouches and the substances they contain. The search terms included: “nicotine pouches”, “tobacco-free nicotine”, “nicotine addiction potential”. Data from selected publications were subjected to qualitative analysis.

**Conclusions:** Nicotine pouches have an impact on human health, both in terms of the systemic effects of nicotine and local effects in the oral cavity. At the same time, the available scientific research on their long-term effects remains limited, making it difficult to fully assess the health risks. For this reason, there is a need for further, studies to better determine their impact on the human body.

**Keywords:** Nicotine, Nicotine Pouches, Smokeless Tobacco, Oral Mucosal Changes, Snus

## 1. Introduction

Oral nicotine pouches have become a rapidly growing category of smoke-free nicotine products, particularly popular among teenagers and young adults. They are marketed as a discreet and “tobacco-free” alternative to traditional products, which increases their appeal but also raises questions about nicotine initiation and the potential shift of some users toward long-term dependence on nicotine products. [1,2] At the same time, nicotine remains a highly addictive substance, and its significance is not limited solely to inducing pleasure or alleviating withdrawal symptoms. [3] The literature emphasizes that exposure to nicotine may perpetuate the use of nicotine products and, during developmental periods, may adversely affect the nervous, respiratory, immune, and cardiovascular systems. [4] The composition of the pouches and the method of nicotine release are also significant for their evaluation. Available studies indicate that the nicotine content in pouches can vary widely, and a high pH may increase nicotine bioavailability through the oral mucosa, meaning that tobacco-free products can still deliver nicotine doses sufficient to induce dependence. [1,5] From a public health perspective, the key question remains the balance of potential benefits and risks. [1] Some reviews suggest that nicotine pouches may deliver nicotine at levels comparable to other nicotine products, while containing fewer toxic compounds than cigarettes, which is sometimes presented as an argument for harm reduction among adult smokers. At the same time, the authors of these studies emphasize that data from independent research remain limited, and a significant portion of the available findings stem from industry-funded studies. [6,7] An important area worthy of separate discussion is local effects within the oral cavity. Systematic reviews have described mucosal changes at the site of exposure, dry mouth, pain, gingival blisters, and other adverse symptoms, although the evidence base remains small and is subject to a high risk of error. [8,9] It is also worth considering the aspects of marketing and risk perception, as the appeal of these products stems not only from nicotine itself but also from characteristics such as flavor, discreet use, and the “tobacco-free” message. [1,2] Such characteristics may increase interest among young people and encourage situational use or concurrent use with other nicotine products, which complicates the assessment of their actual health impact. [6] Another topic worth discussing is the role of the product’s physicochemical properties, including the form of nicotine and its release parameters, as these can influence the rate of absorption and the potency of the addictive effects. The broader literature on new nicotine products shows that regulating nicotine concentration alone may be insufficient if the product’s composition, pH, flavors, and actual usage patterns are not also taken into account. [5,10] In the context of this review, regulatory and epidemiological issues are also particularly important, such as product availability, differences in national policies, youth exposure, concurrent use with cigarettes or e-cigarettes, and the lack of long-term safety studies. For this reason, the aim of this review is to compile current data on the potential harm of nicotine pouches, with particular attention to the mechanisms of nicotine action, local effects in the oral cavity, the risk of addiction,

marketing appeal, and gaps in the evidence that limit the certainty of conclusions. The authors' aim in this study is to review the available literature in order to identify the potential health effects of using nicotine pouches.

## **2. Materials and Methods**

This literature review was conducted to evaluate the health effects associated with the use of smoke-free nicotine alternatives, including electronic cigarettes, heated tobacco products, nicotine pouches, and other non-combustible nicotine delivery systems. Relevant scientific articles were identified through searches of electronic databases such as PubMed, ResearchGate, and Google Scholar. The search strategy included combinations of keywords including “smoke-free nicotine products,” “electronic cigarettes,” “heated tobacco products,” “nicotine pouches,” “health effects,” and “harm reduction.” The selected literature was analyzed and synthesized to provide an overview of the current evidence regarding the potential benefits and risks of smoke-free nicotine alternatives.

### **Inclusion criteria comprised:**

Only peer-reviewed articles published in English were included. Studies focusing on adult populations, toxicological analyses, cardiovascular and respiratory outcomes, addiction potential, and comparative risks versus conventional cigarette smoking were considered.

### **Exclusion criteria included:**

Articles unrelated to human health effects or lacking sufficient scientific relevance were excluded.

### **Selected studies were categorized into thematic domains:**

- Physiological effects of nicotine on the human body
- The impact of substances contained in nicotine pouches on the oral mucosa.
- Social aspect of using tobacco-free products
- Legal status of Nicotine Pouches in the European Union

## **3. Physiological Effects of Nicotine on the Human Body**

Nicotine is a pyridine alkaloid with potent biological effects that acts on the human body primarily by activating nicotinic acetylcholine receptors (nAChRs), which are located in both the central and peripheral nervous systems. After administration, nicotine rapidly penetrates biological membranes and reaches the brain within a few seconds, due to its lipophilicity and low molecular weight. [11] At the

molecular level, nicotine acts as an agonist of nAChRs, particularly the  $\alpha 4\beta 2$  and  $\alpha 7$  subtypes. Activation of these receptors leads to neuronal depolarization and an increased influx of sodium and calcium ions, resulting in the release of numerous neurotransmitters, including dopamine, norepinephrine, serotonin, and glutamate. Of particular importance is the stimulation of the mesolimbic dopaminergic system, which is responsible for nicotine's addictive properties. [12, 13] Nicotine also has a significant effect on the cardiovascular system. By activating receptors in the autonomic ganglia and the adrenal medulla, it leads to increased secretion of catecholamines, primarily epinephrine and norepinephrine. As a result, an increased heart rate (tachycardia), elevated blood pressure, and increased myocardial contractility are observed. Long-term exposure to nicotine may contribute to endothelial dysfunction and an increased risk of cardiovascular disease. [14] In the respiratory system, nicotine does not have a direct irritant effect comparable to that of tobacco smoke; however, it indirectly affects respiratory regulation through the central nervous system. It may also modulate the inflammatory response and the function of immune cells, including macrophages and neutrophils. [15] Within the gastrointestinal tract, nicotine affects intestinal motility and the secretion of digestive juices. It stimulates the parasympathetic nervous system, which can lead to increased intestinal peristalsis, but at the same time, through its central effects, it can reduce appetite. The anorexic effect of nicotine is linked to its influence on the hypothalamic centers regulating appetite and the modulation of neuropeptides such as neuropeptide Y and pro-opiomelanocortin. [16] Nicotine also exhibits dose-dependent toxicity. In acute poisoning, it can cause nausea, vomiting, excessive salivation, cardiac arrhythmias, seizures, and, in extreme cases, respiratory failure resulting from neuromuscular junction blockade. This mechanism is associated with initial stimulation followed by desensitization of nAChRs. [17] Nicotine pouches represent a new category of tobacco-free oral nicotine delivery systems in which the alkaloid is delivered through the oral mucosa. When a pouch is placed in the oral vestibule, nicotine diffuses through the stratified squamous epithelium, allowing for its direct absorption into the systemic circulation, bypassing first-pass metabolism in the liver. The rate of absorption depends on the pH of the environment (alkalization increases the unionized fraction of nicotine), its concentration, and the duration of exposure. [18, 19] Compared to traditional combustible tobacco products, nicotine pouches are characterized by a slower rise in peak blood concentration ( $C_{max}$ ); however, the total bioavailability of nicotine may be comparable at sufficiently high doses. The pharmacokinetic profile is similar to that of other oral forms of nicotine, such as gum or lozenges, although some studies indicate higher and more stable concentrations depending on the product formulation. [20, 21] Although nicotine pouches do not contain tobacco or combustion products, they remain a source of pharmacologically active nicotine, which has a multifaceted effect on the human body. Their use leads to the activation of nicotinic acetylcholine receptors, resulting in stimulation of the central nervous system, increased secretion of catecholamines, and modulation of numerous neurohormonal processes. Consequently, effects observed include an increase in heart rate and blood pressure, impacts on cognitive function, and significant addictive potential. [14, 22] At the same time, the lack of exposure to toxic combustion byproducts, such

as carbon monoxide and polycyclic aromatic hydrocarbons, suggests a lower risk compared to traditional cigarette smoking. This does not mean, however, that nicotine pouches are harmless to health—nicotine itself has a negative impact on the cardiovascular system, can impair endothelial function, and affect metabolism and the nervous system. Furthermore, there is evidence suggesting their potential to contribute to the development of addiction, particularly among young people. [23, 24]

#### **4. The direct effect of nicotine pouches on the oral mucosa**

Nicotine pouches are used by placing the product in the oral vestibule, most often near the upper gum line, which results in direct and prolonged contact with the mucous membrane. The stratified squamous epithelium of the oral cavity acts as a protective barrier, but it is also the site of active nicotine absorption. This process occurs mainly through passive diffusion, and its effectiveness depends on the pH of the environment, tissue hydration, and the properties of the pouch formulation, including the content of alkalizing substances. [18] The direct effect of pouches on the oral mucosa is primarily irritating. Users often report symptoms such as a burning sensation, stinging, or dryness at the application site. The mechanism behind these symptoms is linked to both the presence of nicotine and technological additives, such as pH regulators, flavorings, and fillers. The alkaline environment that facilitates nicotine absorption can simultaneously lead to local damage to epithelial cells and disruption of the mucosal barrier's integrity. [25] Prolonged exposure of the mucous membrane to nicotine can lead to adaptive changes, such as hyperkeratosis (epithelial thickening) and localized tissue thickening. These phenomena have been widely described in the context of traditional oral tobacco products (e.g., snus); however, in the case of nicotine pouches, available data suggest that these changes may occur less frequently and be less severe, which is associated with the absence of many toxic components present in tobacco. [26, 27] Another important aspect is the effect of nicotine on microcirculation within the mucous membrane. Nicotine has a vasoconstrictive effect, leading to narrowing of blood vessels and reduced blood flow in tissues. This can result in impaired regenerative processes, delayed healing of microtraumas, and increased susceptibility to mechanical damage. [28] Nicotine also affects the local immune response. It has been shown to modulate the activity of immune system cells, such as neutrophils and macrophages, and to influence the production of pro-inflammatory cytokines. In the context of the oral cavity, this may lead to a shift in the microbial balance and increased susceptibility to infections or inflammation, although data on nicotine pouches remain limited. [15] In addition, attention should be paid to the potential effects of the flavorings and excipients contained in the pouches. Some of these may have irritating or allergenic effects, which, when combined with the effects of nicotine, may exacerbate local adverse reactions [24]

#### **5. Social Aspect of Using Nicotine Pouches**

A key feature of nicotine pouches is that they do not involve combustion and do not produce aerosol or smoke, which distinguishes them from both traditional tobacco products and electronic nicotine delivery

systems. As a result, their use is virtually invisible to others and does not involve the release of substances into the external environment. This feature allows users to use the pouches in public places where restrictions on smoking or the use of e-cigarettes apply, such as public transportation, workplaces, or enclosed spaces. [24] The ability to use these products discreetly is one of the main factors contributing to their appeal. From a behavioral and social perspective, this can lead to more frequent and continuous nicotine intake throughout the day, as users are not constrained by anti-smoking regulations or social norms to the same extent as they are when smoking. As a result, a constant level of nicotine in the body may be maintained, which potentially increases the risk of developing and perpetuating addiction. [11] It should also be emphasized that the use of pouches in public places raises significant regulatory concerns. The lack of clear regulations in many countries may make it difficult to monitor their use, particularly in the context of protecting minors. Furthermore, the discreet nature of consumption makes it difficult to identify users, which may encourage nicotine use among groups that have not previously been exposed to it. [29]

## **6. Legal status of nicotine pouches in the European Union**

Within the European Union, the legal status of nicotine pouches remains highly diverse due to the absence of harmonized regulations under the current European Union Tobacco Products Directive (TPD). Unlike conventional tobacco-containing snus, whose commercial sale is prohibited throughout the EU apart from Sweden, tobacco-free nicotine pouches occupy a regulatory gray area because they do not contain tobacco leaf yet deliver pharmacologically active nicotine. As a result, Member States have adopted different legislative approaches depending on national public health priorities and interpretations of existing tobacco and consumer safety laws. Countries such as Sweden, Denmark, Finland, and the Czech Republic currently permit the sale of nicotine pouches, although regulations concerning maximum nicotine concentration, flavor availability, health warnings, packaging, and age restrictions vary substantially. In contrast, Belgium has implemented a complete ban on nicotine pouches, while the Netherlands has introduced strict limits on nicotine content and marketing practices. Germany and several other EU countries continue to debate whether nicotine pouches should be regulated as tobacco-related products, pharmaceutical products, or general consumer goods. [30] Recent scientific and public health discussions emphasize that the rapidly increasing popularity of nicotine pouches among adolescents and young adults has become a major concern for European regulators. Flavored products, attractive packaging, and aggressive online marketing strategies are considered factors that may increase experimentation and nicotine dependence among non-smokers and underage users. At the same time, some researchers and policymakers argue that nicotine pouches may represent a harm-reduction alternative for adult cigarette smokers seeking smoke-free nicotine delivery systems with potentially lower toxicant exposure compared with combustible tobacco products. This dual perception has contributed to ongoing legal and ethical debates regarding the balance between smoking cessation potential and youth protection. Furthermore, the lack of unified EU-wide legislation creates

inconsistencies in taxation, product standards, cross-border sales, and advertising restrictions, which may complicate the enforcement of public health policies across Member States. Current literature suggests that the European Union may require a comprehensive regulatory framework specifically dedicated to emerging nicotine products in order to ensure consistent consumer protection, standardized product safety assessment, and effective prevention of nicotine initiation among young populations. [31,32]

## **7. Discussion**

Nicotine pouches represent a rapidly emerging category of nicotine delivery systems that combine features of reduced exposure to combustion-related toxicants with the continued pharmacological activity of nicotine. The evidence reviewed in this study indicates that, despite being marketed as “tobacco-free,” these products are not biologically inert and exert systemic effects comparable to other forms of nicotine exposure. Their mechanism of action—mediated through nicotinic acetylcholine receptors—leads to central nervous system stimulation, cardiovascular activation, and a well-established potential for dependence. From a toxicological and clinical perspective, the absence of combustion products suggests a potentially lower health risk compared to conventional cigarette smoking. However, this relative risk reduction should not be misinterpreted as safety. Nicotine itself remains a substance with documented adverse effects on cardiovascular function, endothelial integrity, metabolic regulation, and neurodevelopment, particularly in younger populations. An important aspect highlighted in this review is the local impact of nicotine pouches on the oral mucosa. Available data suggest that their use may be associated with irritation, epithelial changes, and alterations in microcirculation and local immune responses. Although these effects may be less pronounced than those observed with traditional oral tobacco products, the current evidence base is limited and does not allow for definitive conclusions regarding long-term safety. The behavioral and social characteristics of nicotine pouch use further complicate their risk profile. Their discreet nature and the ability to use them in public spaces without restriction may promote more frequent and sustained nicotine intake, potentially reinforcing addiction patterns. Additionally, product features such as flavoring and marketing strategies may increase their attractiveness among adolescents and non-smokers, raising concerns about nicotine initiation and dual use with other products. A critical limitation identified across the literature is the scarcity of independent, long-term studies. A significant proportion of available data originates from industry-funded research, which underscores the need for cautious interpretation and highlights gaps in knowledge regarding chronic exposure, population-level effects, and regulatory outcomes. In summary, nicotine pouches may represent a less harmful alternative for current smokers when considered within a harm reduction framework; however, they are not risk-free. Their systemic effects, potential for addiction, local oral health implications, and growing popularity among young individuals necessitate further high-quality, independent research. conclusion, the legal status of nicotine pouches within the European Union remains inconsistent and fragmented due to the lack of harmonized regulations under the current

Tobacco Products Directive. While some Member States permit the sale of nicotine pouches under varying regulatory conditions, others have introduced strict limitations or complete bans in response to public health concerns. These differences reflect ongoing uncertainty regarding the classification, safety, and long-term health implications of tobacco-free nicotine products. The growing popularity of nicotine pouches, particularly among young consumers, highlights the urgent need for a unified European regulatory framework that would establish consistent standards for nicotine concentration, marketing practices, labeling, and consumer protection. Further scientific research and coordinated public health policies are necessary to balance potential harm-reduction benefits for adult smokers with the prevention of nicotine initiation among adolescents and non-smokers. Future studies should focus on long-term health outcomes, patterns of use, and the impact of regulatory strategies to better inform public health policies and clinical recommendations.

## **8. Conclusions**

The findings of this review indicate that nicotine pouches are not risk-free despite the absence of tobacco combustion. Although they may reduce exposure to harmful combustion-related toxicants compared with traditional cigarettes, nicotine itself remains a biologically active and addictive substance that affects the cardiovascular, nervous, and immune systems. Available evidence suggests that nicotine pouches may cause local oral mucosal irritation, alterations in microcirculation, and epithelial changes, although these effects appear less severe than those associated with traditional smokeless tobacco products. An important concern is the growing popularity of nicotine pouches among adolescents and young adults, largely due to their discreet use, flavored formulations, and attractive marketing strategies. The lack of harmonized regulations within the European Union further complicates public health control and consumer protection. Furthermore, greater public health discussion and educational efforts regarding nicotine pouches are necessary, particularly because these products are often marketed as “safer” or “tobacco-free” alternatives. Although they may present a lower toxicological risk compared with combustible tobacco products, they are not completely risk-free and may still negatively affect cardiovascular health, oral tissues, and the development of nicotine dependence. Increasing awareness among consumers, healthcare professionals, and policymakers is essential to prevent the misconception that nicotine pouches are harmless products, especially among adolescents and non-smokers. Current literature also remains limited by the shortage of long-term independent studies. Therefore, further research is necessary to better understand the chronic health effects, addiction potential, and public health impact of nicotine pouch use.

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