# PAS 8877:2022

# Tobacco-free oral nicotine pouches – Composition, manufacture and testing – Specification

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# Contents

# Foreword

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The provisions of this PAS are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is "shall".

*Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.*

Where words have alternative spellings, the preferred spelling of the Shorter Oxford English Dictionary is used (e.g. "organization" rather than "organisation").

Requirements in this PAS are drafted in accordance with *Rules for the structure and drafting of UK standards:2017*, subclause **G.1.1**, which states, "Requirements should be expressed using wording such as: 'When tested as described in Annex A, the product shall ...'". This means that only those products that are capable of passing the specified test will be deemed to conform to this PAS.

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**Compliance with a PAS cannot confer immunity from legal obligations.**

In particular, attention is drawn to the following specific regulations:

- General Product Safety Regulations 2005 [1];
- Retained CLP Regulation (EU) No. 1272/2008 as amended for Great Britain [2].

# 0 Introduction

## 0.1 General

Tobacco-free oral nicotine pouches are a rapidly growing category of products in the UK. It is therefore important to provide requirements governing their composition, safety and quality across the complete life cycle from manufacturer to consumer.

## 0.2 Motivation behind the creation of PAS 8877

In order for manufacturers, importers, distributors and retailers of tobacco-free oral nicotine pouches to be able to provide quality and safety assurances to consumers, the public and regulators, it is important to control how products are made and what goes into them. The requirements specified in this PAS are provided to assist manufacturers, importers, distributors and retailers in assessing their products for these factors.

## 0.3 Safety, quality and performance specifications

Safety and quality specifications are necessary to provide minimum expectations for producers and reassurance to consumers, the public and regulators that product safety and quality is maintained across batches and can be reliably demonstrated with documentary evidence. There is also a need to identify analytical methodologies to enable laboratories to test tobacco-free oral nicotine pouches for compliance with the requirements of this PAS.

# 1 Scope

This PAS specifies requirements for the composition, manufacture and testing of tobacco-free oral nicotine pouches through:

a) requirements for ingredients and materials;
b) limits for nicotine contents, pH characteristics and water activity of the pouches; and
c) product information and labelling.

This document also provides guidance on suitable test methods for measurement of nicotine content, pH and water activity.

This PAS is applicable to pre-portioned, tobacco-free oral nicotine pouches exclusively intended for oral use by placing them between the gum and buccal mucosa for a period of time, to facilitate uptake of the nicotine via the oral mucosa, followed by disposal of the pouch after use.

This PAS is intended for manufacturers, importers, distributers and retailers involved in the production and sale of tobacco-free oral nicotine pouches, and for use in laboratories and testing houses engaged in measurements of these pouches.

The PAS does not cover:

- pre-portioned, tobacco-free oral nicotine pouches in which the nicotine is not of natural origin;
- smokeless tobacco products, such as moist snuff, tobacco oral pouches, snus, nasal snuff, chewing tobacco or any other tobacco-containing smokeless tobacco products;
- licensed medicinal nicotine products, such as nicotine replacement therapies (NRT);
- products that are subject to an authorization requirement under Directive 2001/83/EC (Community code relating to medicinal products for human use) [3] or to the requirements set out in Directive 93/42/EEC (Medical Device Directive) [4]; or
- inhaled-nicotine products, such as cigarettes, other combusted tobacco products, tobacco-heating products or e-cigarettes.

The PAS does not provide a method for assessing the health risks or potential reduced health risks of tobacco-free oral nicotine pouches.

This PAS is intended for use in the UK.