



SLOVENSKI STANDARD

oSIST prEN 17633:2021

01-april-2021

Splošna načela in zahteve za preskušanje kakovosti in ravni nikotina v e-tekočinah

General principles and requirements for testing for quality and nicotine levels of e-liquids

Allgemeine Grundsätze und Anforderung für die Prüfung der Qualität und des Nikotingehalts von E-Liquids

Principes généraux et exigences pour les essais de qualité et la détermination de la teneur en nicotine des e-liquides

ITeH STANDARD PREVIEW
(standards.iteh.ai)

Ta slovenski standard je istoveten z: **oSIST prEN 17633:2021 prEN 17633**

<https://standards.iteh.ai/catalog/standards/sist/0d782b71-deba-4885-b44e-d7afdc51d487/osist-pren-17633-2021>

ICS:

65.160	Tobak, tobačni izdelki in oprema	Tobacco, tobacco products and related equipment
--------	----------------------------------	---

oSIST prEN 17633:2021

en,fr,de

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[oSIST prEN 17633:2021](https://standards.iteh.ai/catalog/standards/sist/0d782b71-deba-4885-b44e-d7afdc51d487/osist-pren-17633-2021)

<https://standards.iteh.ai/catalog/standards/sist/0d782b71-deba-4885-b44e-d7afdc51d487/osist-pren-17633-2021>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

DRAFT
prEN 17633

January 2021

ICS 65.160

English Version

General principles and requirements for testing for quality and nicotine levels of e-liquids

Principes généraux et exigences pour les essais de
qualité et la détermination de la teneur en nicotine des
e-liquides

Allgemeine Grundsätze und Anforderung für die
Prüfung der Qualität und des Nikotingehalts von E-
Liquids

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 437.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents		Page
European foreword		3
Introduction		4
1	Scope.....	5
2	Normative references.....	5
3	Terms and definitions.....	5
4	General requirements.....	7
5	Compounds of interest.....	7
6	E-liquids testing.....	7
7	Technical records	10
Bibliography		11

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[oSIST prEN 17633:2021](https://standards.iteh.ai/catalog/standards/sist/0d782b71-deba-4885-b44e-d7afdc51d487/osist-pren-17633-2021)

<https://standards.iteh.ai/catalog/standards/sist/0d782b71-deba-4885-b44e-d7afdc51d487/osist-pren-17633-2021>

European foreword

This document (prEN 17633:2021) has been prepared by Technical Committee CEN/TC 437 “Electronic cigarettes and e-liquids”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[oSIST prEN 17633:2021](https://standards.iteh.ai/catalog/standards/sist/0d782b71-deba-4885-b44e-d7afdc51d487/osist-pren-17633-2021)

<https://standards.iteh.ai/catalog/standards/sist/0d782b71-deba-4885-b44e-d7afdc51d487/osist-pren-17633-2021>

Introduction

E-liquid is a term describing liquid either prefilled in vaping products, or available in other forms so that consumers can fill the reservoirs or soak the wicking material of vaping products. E-liquids may or may not contain nicotine. In either case, they generally contain glycerol and/or propylene glycol together with additional flavouring components. E-liquids are intended to be aerosolised for inhalation by the user.

This document establishes the general principles and requirements for the testing of quality and nicotine levels in e-liquids for vaping products in their fully produced state.

The recommendations given in this document are relevant to the vast majority of product types currently available, as well as to those that will be developed. Not all elements of these recommendations will apply to every type of product, but the definitions may be used to identify recommendations for specific products within the product sector.

This document can provide state of the art guidance for the testing of e-liquids for quality and nicotine level; however, in cases where national regulations currently exist, said regulations take precedence over this document.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[oSIST prEN 17633:2021](https://standards.iteh.ai/catalog/standards/sist/0d782b71-deba-4885-b44e-d7afdc51d487/osist-pren-17633-2021)

<https://standards.iteh.ai/catalog/standards/sist/0d782b71-deba-4885-b44e-d7afdc51d487/osist-pren-17633-2021>

1 Scope

This document specifies the quality testing of e-liquids for vaping products in their fully produced form (“finished e-liquid”), whether containing nicotine or not. It is also applicable to testing of e-liquids when extracted from prefilled cartridges and similar e-liquid presentations to consumers.

This document is intended to be read in conjunction with CEN documents WI 00437001, *General principles for manufacturing, filling and holding e-liquids for prefilled containers or products*, and WI 00437023, *E-liquid Ingredients*.

NOTE Testing for undesirable constituents is outside the scope of this document because their presence in final e-liquid is limited by controls at the ingredient level. The maximum level of undesirable constituents is set in the ingredient specification and monitored by testing at a frequency determined appropriate by the manufacturer.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

WI 00437001,¹ *General principles for manufacturing, filling and holding e-liquids for prefilled containers or products*

ISO 20714:2019, *E-liquid — Determination of nicotine, propylene glycol and glycerol in liquids used in electronic nicotine delivery devices — Gas chromatographic method*

3 Terms and definitions (standards.iteh.ai)

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1

e-liquid

base liquid, which may or may not contain nicotine and/or ingredients, intended for transformation into an aerosol by an electronic cigarette

3.2

vaping product

product that vapourises e-liquid to generate an inhalable aerosol carried by air drawn through the device by the user

Note 1 to entry: Vaping products also referred to as electronic cigarette, e-cig, vapour product, personal vapouriser or ENDS/ENNDS.

Note 2 to entry: Vaping products differ from tobacco products in that they do not contain tobacco.

¹ In preparation.

prEN 17633:2021 (E)**3.3****nicotine**

(S)-3-(1-methyl-2-pyrrolidinyl) pyridine, conforming to the Chemical Abstracts Service nomenclature under n° CAS: 54-11-5

3.4**e-liquid cartridge**

e-liquid container that can be loaded directly into an e-cigarette, which can be disposable

3.5**compound**

individual chemical substance that usually has a unique CAS#

3.6**constituent**

individual chemical substance within an ingredient

3.7**ingredient**

any compound or mixture of compounds intentionally included in an e-liquid

EXAMPLE

Vegetable glycerol, propylene glycol, nicotine, flavourings

3.8**flavouring**

ingredient that imparts smell and/or taste

iTeh STANDARD PREVIEW
(standards.iteh.ai)

3.9**manufacturer**

any entity which manufactures a product or has a product designed or manufactured, and/or markets that product under their name or trademark

[oSIST prEN 17633:2021](https://standards.iteh.ai/catalog/standards/sist/0d782b71-deba-4885-b44e-11f5-52537a000000/pr-en-17633-2021)

[https://standards.iteh.ai/catalog/standards/sist/0d782b71-deba-4885-b44e-](https://standards.iteh.ai/catalog/standards/sist/0d782b71-deba-4885-b44e-11f5-52537a000000/pr-en-17633-2021)

[11f5-52537a000000/pr-en-17633-2021](https://standards.iteh.ai/catalog/standards/sist/0d782b71-deba-4885-b44e-11f5-52537a000000/pr-en-17633-2021)

3.10**product batch**

products manufactured in a defined production schedule and specified volume from identified components/base ingredients according to the batch specification

3.11**batch specification**

document itemizing the inputs and processes for manufacturing a specific product batch that can be used for batch traceability purposes

3.12**release specification**

list of attributes defined by the manufacturer, against which all batches of manufactured product are checked and recorded

3.13**reference e-liquid**

e-liquid containing specific ingredients of a known quantity, to be used as a reference standard

4 General requirements

4.1 E-liquids testing

E-liquids testing (analysis) shall be required:

- To demonstrate e-liquids meet with pre-established specification.
- To quantify compounds of interest with an adequate accuracy.
- To enable the establishment and maintenance of records, either in paper or electronic form, on the determined test results of the vaping product.

4.2 E-liquids categories

E-liquids can belong to one of the following different categories:

- E-liquids which contain nicotine
- E-liquids which do not contain nicotine

5 Compounds of interest

5.1 Main compounds

This list is not exhaustive:

- nicotine
- propylene glycol
- glycerol
- water

ITeH STANDARD PREVIEW
(standards.iteh.ai)
oSIST prEN 17633:2021
<https://standards.iteh.ai/catalog/standards/sist/0d782b71-deba-4885-b44e-d7afdc51d487/osist-pren-17633-2021>

5.2 Undesirable constituents

The presence of undesirable constituents in finished e-liquid shall be controlled at the ingredient level and set in the ingredient specifications for all flavourings that are known to potentially contain such undesirable constituents.

The control of undesirable constituents shall also be informed by the production process as indicated in WI 00437001. Testing for undesirable constituents at the ingredient level shall be conducted at a frequency determined appropriate by the manufacturer.

6 E-liquids testing

6.1 General

Testing of finished e-liquids shall be made in accordance with ISO 20714:2019, or by any other validated method with performance characteristics at least equal to ISO 20714:2019, at the point of manufacture.

prEN 17633:2021 (E)**6.2 E-liquids which do not contain nicotine**

E-liquid shall be considered as not containing nicotine when nicotine ingredient has not been intentionally included in the e-liquid formulation, and subsequent testing of the finished e-liquid has determined the concentration is below 0,5 mg/ml.

The quantitation limit of the analytical method described in ISO 20714:2019 is 0,5 mg/g. Upon testing the density of the liquid shall be taken into account and the final result reported in mg/ml.

NOTE The specified requirement for e-liquid to be considered as not containing nicotine has no regulatory status and is only intended to provide guidance in the absence of existing national regulation.

To ensure compliance with national regulation based on where the product will be marketed, the determination of nicotine content shall be performed per batch of finished e-liquid.

6.3 E-liquids which contain nicotine

Testing of finished e-liquids shall demonstrate that product label claims for nicotine concentration are accurate to within the following:

≤ 20,00 mg/ml (±) 10 %

≥ 20,01 mg/ml (±) 5 %

To ensure compliance with national regulation based on where the product will be marketed, the determination of nicotine content shall be performed per batch of finished e-liquid.

6.4 Determination of propylene glycol and glycerol content of finished e-liquids

The propylene glycol and glycerol content of finished e-liquids shall preferably be tested with ISO 20714:2019 or by any other validated method with performance characteristics at least equal to ISO 20714:2019.

In the absence of specific requirements detailed in national regulation, propylene glycol and glycerol content testing shall be performed at a frequency as determined appropriate by the manufacturer to validate conformity with pre-established e-liquid specification.

6.5 Determination of water content of finished e-liquids

Where appropriate, the water content of finished e-liquids shall be tested with an appropriately verified and recorded method to validate conformity with pre-established e-liquid specification. Any explicit labelling claim for water-free e-liquid shall be supported by the manufacturer with objectively verifiable tests.

In the absence of specific requirements detailed in national regulation, water content testing shall be performed at a frequency as determined appropriate by the manufacturer to validate conformity with pre-established e-liquid specification.

6.6 Determination of pH of finished e-liquids

Where appropriate, the pH of finished e-liquids shall be tested with an appropriately verified and recorded method to validate conformity with pre-established e-liquid specification.

In the absence of specific requirements detailed in national regulation, pH testing shall be performed at a frequency as determined appropriate by the manufacturer to validate conformity with pre-established e-liquid specification.

The pH of a finished e-liquid can be measured at a dilution level of 7:1 to 9:1 water: e-liquid. To standardize the pH meter, select two buffer solutions for standardization whose difference in pH does not exceed 4 units and such that the expected pH of the diluted e-liquid under test falls between them.