SLOVENSKI STANDARD
SIST-TS CEN/TS 17633:2022

01-november-2022

Splošna načela in zahteve za preskušanje kakovosti in vsebnosti nikotina v tekočinah za elektronske cigarete

General principles and requirements for testing of quality and nicotine levels of electronic cigarette liquids

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

Principes généraux et exigences concernant les essais relatifs à la qualité et aux teneurs en nicotine des liquides pour cigarettes électroniques

Ta slovenski standard je istoveten z: **CEN/TS 17633:2022**

ICS:

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

SIST-TS CEN/TS 17633:2022 **en,fr,de**

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN/TS 17633

September 2022

ICS 65.160

English Version

General principles and requirements for testing of quality and nicotine levels of electronic cigarette liquids

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

This Technical Specification (CEN/TS) was approved by CEN on 1 August 2022 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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

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Ref. No. CEN/TS 17633:2022 E

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European foreword

This document (CEN/TS 17633:2022) has been prepared by Technical Committee CEN/TC 437 “Electronic cigarettes and e-liquids”, the secretariat of which is held by AFNOR.

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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 can or cannot 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.

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 can be used to identify recommendations for specific products within the product sector.

The content is applicable to manufacturers and distributors in Europe and forms a guide for regulators, enforcement authorities and commercial operators in the area. It is also applicable to consultancies, laboratories and testing houses engaged in or advising on, the manufacturing of e-liquids and e-liquid components.

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.

1 Scope

This document specifies the manufacturing quality testing of e-liquids for vaping products in their fully produced form, i.e. “finished e-liquid”, at the point of manufacture, whether containing nicotine or not.

This document is intended to be read in conjunction with EN 17647 and EN 17648.

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 are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 17647, *General principles for manufacturing, filling and holding e-liquids for prefilled containers or products*

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

3 Terms and definitions

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 https://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
e-liquid
base liquid, which might or might not contain nicotine and/or ingredients, intended for transformation into an aerosol by a vaping product

3.2
finished e-liquid
base liquid, which might or might not contain nicotine and/or ingredients, intended for transformation into an aerosol by a vaping product

Note 1 to entry: Finished e-liquid can refer to bulk e-liquid stored in large volume vessels prior to final filling into individual refill containers or e-liquid that has been filled into refill containers or cartridges.

3.3
vaping product
product that vaporizes e-liquid to generate an inhalable aerosol carried by air drawn through the device by the user

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

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

3.4
nicotine
(S)-3-(1-methyl-2-pyrrolidinyl) pyridine, conforming to the Chemical Abstracts Service nomenclature under CAS RN®[1] 54-11-5

3.5
e-liquid cartridge
e-liquid container that can be loaded directly into a vaping product, which can be disposable

3.6
compound
individual chemical substance that usually has a unique CAS RN®[1]

3.7
constituent
individual chemical substance within an ingredient

3.8
ingredient
any compound or mixture of compounds intentionally included in an e-liquid

EXAMPLES Vegetable glycerol, propylene glycol, nicotine, flavourings.

3.9
flavouring
ingredient that imparts smell and/or taste

3.10
manufacturer
any entity which manufactures a product or has a product designed or manufactured, and/or markets that product under their name or trademark

4 General requirements

4.1 E-liquids testing

E-liquids testing (analysis) shall be required:

— to demonstrate that e-liquids meet with their pre-established specification;

— to quantify relevant compounds with an adequate level of accuracy, accounting for uncertainty of measurement;

— to enable the establishment and maintenance of records, either in paper or electronic form, on the determined test results of the vaping product.

[1] CAS Registry Number® (CAS RN®) is a trademark of CAS corporation. This information is given for the convenience of users of this document and does not constitute an endorsement by CEN of the product named. Equivalent products may be used if they can be shown to lead to the same results.

4.2 E-liquids categories

E-liquids can belong to either of the following categories:

— “E-liquids to which nicotine has been intentionally added”;

— “Nominally nicotine-free e-liquids”.

5 Ingredients

5.1 Main compounds

This list is not exhaustive:

— “nicotine”;

— “propylene glycol”;

— “glycerol”;

— “water”.

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 ingredients, including 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 EN 17647. Testing for undesirable constituents at the ingredient level shall be conducted at an appropriate frequency determined by the manufacturer.

6 E-liquids testing

6.1 General

Testing of finished e-liquids shall be done in accordance with ISO 20714, or by any other validated method at the point of manufacture.

6.2 Nominally nicotine-free e-liquids

Nominally nicotine-free e-liquids are e-liquids where nicotine 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.

Upon testing, the density of the liquid shall be considered, and the final result reported in mg/ml. The e-liquid density should be determined by a verified method or calculated from main ingredient composition.

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.

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

6.3 E-liquids to which nicotine has been intentionally added

Testing of finished e-liquids shall demonstrate the that nicotine concentration is accurate with regards to the target nicotine level in the pre-established e-liquid specification, to within (±)10 % tolerance range of the e-liquid specification. The nicotine content of finished e-liquids can be tested with ISO 20714 or with other validated methods.

If ISO 20714 is used, method verification shall be performed to ensure the method has a suitable level of accuracy for the product to be tested, to test within the (±)10 % tolerance range. If other validated methods are used, then these methods shall be fit for purpose to test within the (±)10 % tolerance range.

NOTE The required accuracy of nicotine content compared to the product label claim, over the duration of the product's shelf life, is specified in EN 17648.

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

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

The propylene glycol and glycerol content of finished e-liquids can be tested with ISO 20714 or with other validated methods.

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 the 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 the 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 the pre-established e-liquid specification.

6.6 Estimation 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 the 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 the pre-established e-liquid specification.

NOTE The pH of a finished e-liquid can be measured within the dilution range of adding seven to nine parts CO_2 free water to one part 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. Perform standardization at the temperature at which the test e-liquid is to be measured. When the pH meter is functioning satisfactorily, rinse the electrodes and cell several times with a few portions of the diluted e-liquid under test. Allow sufficient time for stabilization before recording the pH value. Use appropriate grade water for dilution of e-liquids under test (e.g. CO_2 free).

6.7 Flavoured e-liquid odour sniff test

For flavoured e-liquids, an odour profile comparison between the finished e-liquid and an authentic sample of the relevant flavour shall be performed to reassure the intended flavour has been used in the manufacture of a batch. The comparison shall be performed in accordance with an appropriate verified