

STN	Prísady do e-kvapalín	STN EN 17648 56 9585
------------	------------------------------	--

E-liquid ingredients

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/22

Obsahuje: EN 17648:2022

135766

EUROPEAN STANDARD

EN 17648

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2022

ICS 65.160

English Version

E-liquid ingredients

Ingrédients des e-liquides

Inhaltsstoffe von E-Liquids

This European Standard was approved by CEN on 27 June 2022.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists 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, Türkiye and United Kingdom.



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

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

EN 17648:2022 (E)

Contents	Page
European foreword	3
Introduction	4
1 Scope.....	5
2 Normative references.....	5
3 Terms, definitions and abbreviations	6
3.1 Terms and definitions	6
3.2 Abbreviations.....	7
4 Ingredient suppliers' selection	8
4.1 Disclosure of e-liquid / flavouring formulation	8
4.2 Supply chain requirements	8
4.3 Change notifications	8
5 Ingredient requirements	9
5.1 Ingredient functions	9
5.2 Ingredient quality.....	9
5.3 Ingredient exclusion criteria.....	10
5.4 Toxicological risk assessment.....	12
6 Finished e-liquid requirements.....	13
6.1 E-liquid integrity.....	13
6.2 E-liquid related emission requirements	14
6.3 E-liquid related product information requirements	14
Annex A (informative) Compounds that should not be used as ingredients in e-liquids	17
Annex B (informative) Undesirable constituents.....	18
Bibliography	20

European foreword

This document (EN 17648:2022) has been prepared by Technical Committee CEN/TC 437 “Electronic cigarettes and e-liquids”, the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2023, and conflicting national standards shall be withdrawn at the latest by February 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: 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 the United Kingdom.

EN 17648:2022 (E)**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 or nicotine salts. 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 related to ingredients used in e-liquids and e-liquid components to ensure an appropriate level of consumer safety.

The content is applicable to producers 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 planning to be engaged in, the safety evaluation of e-liquids and e-liquid components.

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 on ensuring the consumer safety of e-liquid ingredients. Note that as a matter of course, in cases where national regulations currently exist, said regulations take precedence over this document.

1 Scope

This document describes requirements related to ingredients used in e-liquids and e-liquid components.

This document:

- specifies ingredient purity and related supply chain requirements;
- specifies ingredient exclusion criteria based on function and toxicological properties;
- specifies the need for a toxicological risk assessment and provides guidance on the content of this as well as specifying competency requirements for those responsible for it;
- specifies nicotine content versus label claim over shelf life and performance characteristics of the analytical method used to measure the nicotine;
- specifies pH limits for the e-liquid;
- provides guidance on the measuring of emissions;
- specifies certain ingredient-related product labelling;
- provides guidance on ingredients that should not be used in e-liquids;
- provides guidance on maximum levels in finished e-liquid for certain undesirable constituents that may occur in natural extracts used as flavourings.

This document does not apply to packaging, vaping devices or refill container materials/ingredients.

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.

CEN/TR 17236, *Electronic cigarettes and e-liquids - Constituents to be measured in the aerosol of vaping products*

CEN/TS 17633¹, *General principles and requirements for testing for quality and nicotine levels of electronic cigarette liquids*

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

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

koniec náhľadu – text ďalej pokračuje v platenej verzii STN

¹ Under preparation. Stage at the time of publication: FprCEN/TS 17633:2022.