SLOVENSKI STANDARD
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Sestavine e-tekočin

E-liquid ingredients

Inhaltsstoffe von E-Liquids

Ingrédients des e-liquides

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

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

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

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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of an identical text or by endorsement, at the latest by February 2023, and conflicting national standards shall be withdrawn at the latest by February 2023.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.

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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 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 17633[1], *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)*

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

3 Terms, definitions and abbreviations

3.1 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

3.1.1
base e-liquid
diluents, that form the bulk or entirety of an e-liquid

3.1.2
compound
individual chemical substance, that usually has a unique CAS RN number

3.1.3
constituent
individual chemical substance within an ingredient

3.1.4
diluent
liquid used in the e-liquid to dilute nicotine and/or flavourings and/or to form the aerosol

3.1.5
e-liquid
base liquid, which may or may not contain nicotine and/or nicotine salts and/or other ingredients, intended for transformation into an aerosol by a vaping device

3.1.6
e-liquid component
mixture or ingredient placed on the market, intended for use in e-liquids

3.1.7
flavouring
ingredient that imparts smell and/or taste

Note 1 to entry: A flavouring can be a substance, e.g. vanillin or a mixture of several substances, e.g. lime oil.

3.1.8
ingredient
compound or mixture of compounds intentionally included in an e-liquid

EXAMPLES glycerol, propylene glycol, nicotine, flavourings.

3.1.9
producer
manufacturer of any e-liquid-containing product, e-liquid component, e-liquid ingredient or related packaging or accompanying documents (e.g. leaflet), supplied to a consumer, whereby the manufacturer, by importing and/or putting his name, trademark or other distinguishing feature on the product presents himself as the entity legally responsible for the item within the relevant jurisdiction

3.1.10
refill container
refill bottle
receptacle containing an e-liquid, which can be used to refill a vaping device

3.1.11
solvent
substance, ordinarily a liquid, in which other materials dissolve to form a solution

3.2 Abbreviations

For the purposes of this document, the following abbreviations apply.

Carc	Carcinogenic
CAS RN	CAS Registry Number
CoE number	Number of a material listed in the Council of Europe's reports on chemically defined flavouring substances and natural sources of flavourings
CLP	Regulation (EC) No. 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, mutagenic and/or reprotoxic
ECHA	European Chemicals Agency
E-number	A code number preceded by the letter E (for Europe), denoting food additives numbered in accordance with EU directives
EP	European Pharmacopoeia
FEMA	Flavor and Extract Manufacturers Association of the United States
FLAVIS	European Union flavouring information system
FL-number	FLAVIS number
GRAS	Generally recognized as safe
IARC	International Agency for Research on Cancer
IOFI	International Organization of the Flavor Industry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
Lact.	Lactation
Muta.	Mutagenic
NTP	National Toxicology Program
Repr.	Reprotoxic
Resp. sens	Respiratory sensitizer
TPD	Tobacco Products Directive
USP	United States Pharmacopeia

4 Ingredient suppliers' selection

4.1 Disclosure of e-liquid / flavouring formulation

The e-liquid producer shall ensure they receive full disclosure of all ingredients used in the finished e-liquid or e-liquid component, including of any flavouring pre-mixes that may be used in the production of an e-liquid. Disclosure information is pivotal for proper risk assessment (see 5.4) and control over potential constituents of concern (see 5.3 and Annex B).

The e-liquid disclosure shall consist of the list of individual ingredients, including their use level or appropriate concentration ranges that are sufficient to inform the risk assessment.

Where the ingredients are individual compounds, there shall be sufficient information to unambiguously identify the specific chemical entity, including stereochemistry information where applicable (typically ensured through identification of appropriate CAS RN and/or FL-number).

Where ingredients consist of extracts of natural raw materials, the producer shall obtain information on the presence and maximum levels of any toxicologically undesirable constituents as identified in Annex B, if the presence of constituents listed in Annex B is suspected based on scientific literature. Sufficient information to perform the toxicological assessment (see 5.3) typically includes identification numbers such as CAS RN, FEMA, JECFA CoE, E-numbers and/or FL-numbers. These numbers generally provide some information on the plant botanical name, the plant part used, and/or the extraction process used which allows the main constituents in the composition of the mixture to be characterized through available literature, where required in the toxicological risk assessment.

If insufficient compositional information is available from the identification information provided by the supplier, for the toxicological risk assessment to support the proposed level of use of the ingredient in the e-liquid, chemical analysis may be used to help identify and/or quantify compounds within the ingredient to further inform the risk assessment.

4.2 Supply chain requirements

All e-liquid ingredients shall be supplied with a unique batch code. The producer's own unique batch code for the finished e-liquid shall ensure traceability back to these individual ingredient batch codes.

For all e-liquid ingredients relevant certificates of analysis and/or certificate of conformity demonstrating compliance with the purity requirement specified in 5.2 shall be made available to the producer.

To ensure sufficient quality in the supply chain, ingredient suppliers accredited for food flavouring or pharmaceutical ingredient production should be used.

4.3 Change notifications

Producers shall ensure their ingredient supply chain informs them of any changes to the supplied ingredients that can affect the composition and/or quality of the ingredients. This can include, but is not restricted to, changes to manufacturing processes, changes to geographical origin(s) of the raw materials used to produce natural extracts, changes to recommended storage conditions and shelf life. The producer shall ensure they have appropriate documentation to demonstrate the modified ingredients still meet the purity requirements as specified in 5.2. Any such changes shall result in a new unique batch number, both for the modified ingredient and the finished e-liquid.

5 Ingredient requirements

5.1 Ingredient functions

E-liquids are expected to consist of only diluent(s) and optionally flavouring(s), nicotine and/or nicotine salts. Substances whose only function is as a preservative or to impart colour to an e-liquid or subsequent aerosol intentionally, shall not be added to e-liquids.

NOTE E-liquids can end up having a colour due to ingredients that have other functions and can change colour over time.

Preservatives may be present as constituents from ingredients, but then their level in the finished e-liquid needs to be taken into account in the toxicological risk assessment. If there are exceptional reasons why other ingredients might be required, such as antioxidants or others, their inclusion shall be justified, taking into account their toxicological profile and all risk-benefit considerations.

5.2 Ingredient quality

All diluents forming the base e-liquid, as well as the nicotine used in e-liquids shall meet appropriate pharmaceutical standards.

Only nicotine meeting recognized pharmaceutical specifications shall be used[2]. Supporting documentation shall include certificate(s) of analysis and/or certificate(s) of conformity. If nicotine salts are used as either an ingoing ingredient, or formed *in situ*, the nicotine used to form the nicotine salts shall be of the before mentioned recognized pharmaceutical grade quality and the acid added shall be equivalent to, or of better quality than European or US food grade quality, with supporting documentation including certificate(s) of analysis and/or certificate(s) of conformity.

Only propylene glycol (CAS RN 57-55-6) meeting recognized pharmaceutical specifications shall be used as a diluent[3]. Supporting documentation shall include certificate(s) of analysis and/or certificate(s) of conformity. Where EP propylene glycol is used, an additional requirement is that the level of di-ethylene glycol contamination shall be controlled to ensure it does not exceed a mass fraction of 0,1 %.

Only glycerol (CAS RN 56-81-5) meeting recognized pharmaceutical specifications shall be used as a diluent[4]. Supporting documentation shall include certificate(s) of analysis and/or certificate(s) of conformity.

Where water is used as diluent, its specifications shall be equivalent to, or better than, European or US pharmaceutical specifications for purified water or water for injection[5]. Supporting documentation shall include certificate(s) of analysis and/or certificate(s) of conformity.

Only ethanol meeting recognized pharmaceutical specifications shall be used as a diluent[6]. Supporting documentation shall include certificate(s) of analysis and/or certificate(s) of conformity.

Flavourings are usually supplied in a solvent. The specifications for such flavouring solvents shall be equivalent to, or better than European or US food grade specifications, with supporting documentation including certificate(s) of analysis and/or certificate(s) of conformity. For clarities' sake, if the flavouring solvent is the same compound that is also used as a diluent in the same e-liquid, the proportion added as

[2] For example: nicotine meeting the requirements specified in the European Pharmacopoeia (EP), Nicotine Monograph, or those specified in the United States Pharmacopeia (USP), Nicotine Monograph.
[3] For example: propylene glycol meeting the requirements specified in the EP Propylene glycol Monograph, or those specified in the USP, Propylene Glycol Monograph.
[4] For example: glycerol meeting either the EP Glycerol Monograph or the USP, Glycerin Monograph.
[5] For example: meeting the requirements of either the Purified Water for Injection Monograph or the Purified Water Monograph from either the EP or the USP.
[6] For example: meeting the requirements of the EP Ethanol (96 percent) or Anhydrous Ethanol Monographs, or the USP Ethanol absolute Monograph.