SLOVENSKI STANDARD
oSIST prEN 17648:2021

01-junij-2021

Sestavine e-tekočin

E-liquid ingredients

Inhaltsstoffe von E-Liquids

Ingrédients des e-liquides

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Ta slovenski standard je istoveten z: **prEN 17648**

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ICS:

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

oSIST prEN 17648:2021 **en,fr,de**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 17648

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ICS 65.160

English Version

E-liquid ingredients

Ingrédients des e-liquides

Inhaltsstoffe 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.

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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.

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

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European foreword

This document (prEN 17648:2021) 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 Enquiry.

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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. 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.

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 on ensuring the consumer safety of e-liquid ingredients; however, in cases where national regulations currently exist, said regulations take precedence over this document.

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1 Scope

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

It does not cover packaging, vaping device 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*

prEN 17647:2021, *General principles and requirements, for filling and holding e-liquids for vaping products, including containers and cartridges*

prEN 17633:2021, *General principles and requirements for testing for quality and nicotine levels of e-liquids*

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

3 Terms, definitions and abbreviations

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3.1 Terms and definitions

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

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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 http://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 have a unique CAS#

3.1.3
constituent
individual chemical substance within an ingredient

3.1.4
contaminant
unwanted and unintended substance or material

3.1.5
diluent
solvent used in the e-liquid to dilute nicotine and/or flavourings and/or to form the aerosol

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3.1.6
e-liquid
base liquid, which may or may not contain nicotine and/or other ingredients, intended for transformation into an aerosol by an electronic cigarette

3.1.7
e-liquid component
mixture or ingredient supplied directly to the consumer, intended for use in e-liquids

3.1.8
flavouring
ingredient that imparts smell and/or taste

3.1.9
ingredient
compound or mixture of compounds intentionally included in an e-liquid

EXAMPLE VG, PG, nicotine, flavourings

3.1.10
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, who, by importing and/or putting his name, trade mark or other distinguishing feature on the product presents himself as the entity legally responsible for the item within the relevant jurisdiction

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3.1.11
refill container
receptacle containing an e-liquid, which can be used to refill a vaping device

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Note 1 to entry: Also called refill bottle.

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3.2 Abbreviations

Carc	carcinogenic
CAS	Chemical Abstracts Service registration 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
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 Reasearch 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	Repiratory sensitizer
TPD	Tobacco Products Directive
USP	United States Pharmacopeia

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4 Ingredient suppliers' selection

4.1 Disclosure of e-liquid / flavour formulation

The e-liquid producer shall ensure they receive full disclosure of all ingredients used in the final 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 5.5) and control over potential constituents of concern (see 5.3).

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 and/or FL-number).

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Where ingredients consist of extracts of natural raw materials, disclosure information shall include the presence and maximum levels of any toxicologically undesirable constituents as identified in 5.3. Sufficient information to perform the toxicological assessment (see 5.5) typically includes identification numbers such as CAS, FEMA, JECFA CoE 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.

Where ingredients consist of mixtures of individual compounds and/or extracts of raw materials, the disclosure information described above for each of the individual compounds and/or extracts of raw materials in the mixture, shall be provided. 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 the main constituents of the natural extract 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 final e-liquid shall ensure traceability back to these individual ingredient batch codes.

All e-liquid ingredients shall be accompanied by the relevant certificates of analysis and/or certificate of conformity demonstrating compliance with the purity requirement specified in 5.2.

To ensure sufficient quality in the supply chain, it is recommended to use ingredient suppliers accredited for food flavour or pharmaceutical ingredient production.

4.3 Change notifications

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Producers shall ensure their ingredient supply chain informs them of any changes to the supplied ingredients that may affect the composition and/or quality of the ingredients. This includes, but is not restricted to, changes to manufacturing process, changes to geographical origin(s) of the raw ingredients 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 final e-liquid.

5 Ingredient requirements

5.1 Ingredient functions

E-liquids are expected to consist of only diluent(s) and optionally flavouring(s) and nicotine. 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 may end up having a colour due to ingredients that have other functions and may change colour over time.

Preservatives may be present as constituents from ingredients, but then their final level 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.

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5.2 Ingredient quality

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

Only nicotine of recognized pharmaceutical grade shall be used[1)]. 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 (2,3-propanediol) of recognized pharmaceutical grade shall be used as a diluent[2)]. 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 0,1 %w/w.

Only glycerol (1,2,3-propanetriol) of recognized pharmaceutical grade shall be used as a diluent[3)]. Supporting documentation shall include certificate(s) of analysis and/or certificate(s) of conformity.

Where water is used as diluent, it shall be equivalent to, or of better quality than European or US pharmaceutical grade quality purified water or water for injection[4)]. Supporting documentation shall include certificate(s) of analysis and/or certificate(s) of conformity.

Only ethanol of recognized pharmaceutical grade shall be used as a diluent[5)]. Supporting documentation shall include certificate(s) of analysis and/or certificate(s) of conformity.

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Flavourings are usually supplied in a solvent. The solvent(s) used for these products 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.

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Except for tobacco extracts, only flavourings, whether natural or artificial, that are also authorized for use in food shall be used.

Examples of these are the flavouring agents listed on the following lists:

- Annex 1 of European Food Regulation EU 1334/2008
- Substances Added to Food Inventory of the United States
- FEMA GRAS listings
- IOFI Global Reference List of Natural Complex Substances / Natural Flavouring Complexes

NOTE The European Union list of flavouring substances can also be consulted in the form of the Food Flavourings Database - FLAVIS.

All shall be of equivalent quality, or better than, European or US food grade quality.

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1) 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.
2) For example: propylene glycol meeting the requirements specified in the EP Propylene glycol Monograph, or those specified in the USP, Propylene Glycol Monograph.
3) For example: glycerol meeting either the EP Glycerol Monograph or the USP, Glycerin Monograph.
4) 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.
5) For example, meeting the requirements of the EP Ethanol (96 percent) Monograph, Anhydrous Ethanol or the USP, Ethanol absolute Monograph.