SLOVENSKI STANDARD
SIST EN 17647:2022

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Splošna načela izdelave, polnjenja in shranjevanja e-tekočin za predhodno napolnjene posode ali izdelke

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

Allgemeine Grundsätze für die Herstellung, Abfüllung und Aufbewahrung von E-Liquids für vorgefüllte Behälter oder Produkte

Principes généraux de fabrication, de remplissage et de conservation des e-liquides pour les récipients de recharge ou les cartouches préremplies

Ta slovenski standard je istoveten z: **EN 17647:2022**

ICS:

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

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EUROPEAN STANDARD

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English Version

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Allgemeine Grundsätze für die Herstellung, Abfüllung und Aufbewahrung von E-Liquids für vorgefüllte Behälter oder Produkte

This European Standard was approved by CEN on 13 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.

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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 17647:2022) 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of an identical text or by endorsement, at the latest by January 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.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 might or might 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 for manufacturing, filling and holding e-liquids for prefilled containers or products.

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; however, in cases where national regulations currently exist, said regulations take precedence over this document.

1 Scope

This document establishes the general principles for manufacturing, filling and holding e-liquids for prefilled containers or products.

FprCEN/TS 17633[1] and FprEN 17648[2] are intended to be used in conjunction with this document.

2 Normative references

There are no normative references in this document.

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
batch number
unique number which identifies a specific product batch

3.2
batch specification
document itemizing the inputs and processes for manufacturing a specific product batch that can be used for batch traceability purposes

3.3
contamination
presence of an unwanted and unintended substance or material

3.4
e-liquid
base liquid, which might or might not contain nicotine and/or other ingredients, intended for transformation into an aerosol by a vaping product

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

3.6
e-liquid homogeneity
variation of property values of the e-liquid, either between separate containers of e-liquid, or to variations within each container

[1] Under preparation. Stage at the time of publication: FprCEN/TS 17633:2022.
[2] Under preparation. Stage at the time of publication: FprEN 17648:2022.

3.7
ingredient
any compound or mixture of compounds intentionally included in an e-liquid

EXAMPLES Vegetable glycerol, Propylene glycol, nicotine, flavourings.

3.8
manufacturer
any entity which manufactures a product or has a product designed or manufactured, and/or markets that product under their name or trademark

3.9
nicotine
(S)-3-(1-methyl-2-pyrrolidinyl) pyridine, conforming to the Chemical Abstracts Service nomenclature under n° CAS: 54-11-5

3.10
prefilled container
receptacle containing an e-liquid, which can be used to refill an open system vaping product

Note 1 to entry: Also called refill bottle.

3.11
product batch
product manufactured in a defined production schedule and specified volume from identified components/base ingredients according to the batch specification

3.12
reservoir
component for holding e-liquid to supply to the atomizer

Note 1 to entry: E-liquid reservoir also refers to tank.

3.13
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 product also referred to as electronic cigarette, vapour product, personal vaporizer or ENDS/ENNDS.

Note 2 to entry: Vaping product differs from tobacco product in that they do not contain tobacco.

4 E-liquid manufacturing

4.1 Quality system

A quality system is required in order to ensure that the products consistently meet applicable requirements and specifications.

A quality system is required:

— to establish, implement and apply an effective and documented quality assurance system;

— to establish and maintain an effective quality control system;

— to establish and maintain appropriate records, either in paper or electronic form, on specifications, formula, processing product, and the various manufacturing operations.

The quality system shall cover the process as described in 4.2.

4.2 Process

4.2.1 Manufacturing facilities

Facilities manufacturing and handling e-liquids shall establish and implement a hazard analysis and risk-based preventive control. The hazard analysis shall consider biological, chemical, and physical hazards which can be present in the product because they occur naturally, are unintentionally introduced, or are intentionally introduced.

Facilities shall also monitor their controls, conduct verification activities to ensure the controls are effective, take appropriate corrective actions, and maintain records documenting these activities.

The requirements for e-liquids shall be applicable to all manufacturing facilities regardless of their locations.

4.2.2 Production equipment

Production equipment that can impact the quality of the ingredients or final product shall be specified, documented and calibrated if required. Production equipment shall not lead to contamination. Heavy metals, micro-biological contaminations and polymers (e.g. PTFE) should be considered.

4.2.3 Process control

The following controls shall be in place to produce predictable consistent vaping products:

— Process description: A full process description shall be available, where all process steps are included and specified.

— Quality control with specified sampling plan and quality parameters for:

  — Incoming material inspection: The manufacturer shall perform a minimum of one test on each batch of material to verify its identity. In the absence of additional manufacturer testing, confirmation shall be provided that each material batch meets requirements/specification (e.g. material batch testing supporting documentation from suppliers). The manufacturer shall have a documented process for evaluation of material suppliers.

  — Process control: Process control procedures and methods that can impact the quality of the ingredients or final product shall be specified and documented.

- Finished goods inspection: Written procedures shall be established and followed for the inspection, review, and approval of finished goods, including packaging and labelling, to determine conformity of finished goods with requirements/specifications prior to release or distribution.

- Shelf life: There shall be a clear shelf life established for the product, with supporting documentation to demonstrate how this was established.

- E-liquid homogeneity: The homogeneity of the e-liquid product between mixing and bottling shall be tested, if required, during the qualification of the production line. The results of these tests can be used to establish the production process. Homogeneity testing should be performed on a sub-set of e-liquid containers from the batch using a suitable sampling scheme. Property values, e.g. nicotine and/or propylene glycol/glycerol concentration, should be measured from each e-liquid container using a suitability validated analytical procedure. Multiple measurements of property values from the same e-liquid container can also be performed. Appropriate statistical methods can be used to assess between e-liquid container variability and within e-liquid container variability of measured values.

— Process monitoring: Appropriate controls shall be established at all stages of manufacturing to ensure intermediate and/or finished products quality.

— In-process controls: Acceptance criteria shall be established and documented for in-process controls.

— Deviations: Any deviation from established procedures shall be documented and explained. Critical deviations shall be investigated, and the investigation and its conclusions shall be documented.

— Authorized person: There shall be an adequate number of personnel qualified by appropriate education, training and/or experience to perform and supervise the manufacture of intermediates and finished products. The responsibilities of all personnel engaged in the manufacture of intermediates and finished products shall be specified in writing. Training shall be regularly conducted by qualified individuals and shall cover, at a minimum, the particular operations that the employee performs, as it relates to the employee's functions. Records of training shall be maintained, and training shall be periodically assessed.

— Working instructions: Working instructions shall be available and established for preparing, reviewing, approving, and distributing, for the production of intermediates and/or finished products according to written procedures.

— Batch release:

  - Batches of bulk e-liquid shall only be released upon verification of conformity with pre-established specifications, which shall include parameters relative to the e-liquid composition (identity and concentrations of main ingredients, including at least nicotine), specific impurities of concern, volume, packaging (identity and quality), and labelling (identity, incl. version). Appropriate sampling methods shall be applied by the manufacturer. Verification versus the release specification shall be documented. More details are specified in FprCEN/TS 17633[1] and FprEN 17648[2].

  - Batches of prefilled containers and prefilled vaping products shall only be released upon verification of conformity with pre-established specifications, which shall include parameters relative to identity of components (tracing the bulk e-liquid by batch number and documentation of batch conformity with pre-established specifications), nicotine concentration of the e-liquid (also in non-nicotine products), volume, packaging (identity and quality) and labelling (identity,