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**Splošna načela izdelave, polnjenja in shranjevanja e-tekočin za 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 préréplées

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**Ta slovenski standard je istoveten z: prEN 17647**

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**ICS:**

65.160	Tobak, tobačni izdelki in oprema	Tobacco, tobacco products and related equipment
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EUROPEAN STANDARD  
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**prEN 17647**

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English Version

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

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

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

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.

This draft European Standard was established by CEN 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.

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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 17647:2021) 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 CEN 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 for manufacturing, filling and holding e-liquids for prefilled containers or products.

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 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.

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## 1 Scope

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

prEN 17633:2021 and prEN 17648:2021 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 <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://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

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### 3.3

#### **vaping products**

product, that vapourises e-liquid to generate an inhalable aerosol carried by air drawn through the device by the user

Note 1 to entry: Vaping products also referred to as electronic cigarette, vapour product, personal vapouriser or ENDS/ENNDS.

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

### 3.4

#### **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

### 3.5

#### **importer**

owner of, or a person having the right of disposal over, products that have been brought into the territory of the European Union

### 3.6

#### **manufacturer**

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

**prEN 17647:2021 (E)****3.7****product batch**

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

**3.8****vaping**

action of generating an aerosol with an airflow from an electronic cigarette

**3.9****e-liquid cartridge**

e-liquid container that can be loaded directly into an e-cigarette, which can be disposable

**3.10****refill container**

receptacle containing an e-liquid, which can be used to refill an open system electronic cigarette

Note 1 to entry: Also called refill bottle.

**3.11****e-liquid reservoir**

component for holding e-liquid to supply to the atomizer

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

**3.12****contaminant**

unwanted and unintended substance or material

**3.13****contamination**

presence of a contaminant

**3.14****ingredient**

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

EXAMPLE

Vegetable glycerol, Propylene glycol, nicotine, flavourings.

**3.15****nicotine**

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

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## 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.

Quality system 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 and processing product, and the various manufacturing operations.

The quality system shall cover process as follows.

### 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 may 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 for domestic and foreign facilities.

#### 4.2.2 Production equipment

Production equipment that can impact the quality of the ingredients or final product shall be defined, documented and calibrated if required. Production equipment may 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 defined
- Quality control with defined 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 defined 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

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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 by the manufacturer, with supporting documentation to demonstrate how this was established
- Homogeneity: The homogeneity of the product between mixing and bottling shall be tested, if required, during the qualification of the production line. The results of these tests may be used to establish the production process
- 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. Confirmation shall be provided that each bulk e-liquid batch conforms with pre-established specifications. More details are specified in documents prEN 17633:2021 and "E-liquid ingredients" (temporary ref: CEN437 WG3 WI 003)
  - Batches of e-liquid refill 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, incl. version). Establishment of specifications shall be done by the manufacturer and not by the importer. Confirmation shall be provided that each batch meets pre-established specifications
  - Batches of finished e-cigarettes (that shall be sold with disassembled prefilled vaping products) shall only be released upon verification of conformity with pre-established specifications, which shall include parameters relative to identity of components, electronic functioning, packaging (identity and quality), and labelling (identity, incl. version and quality). Confirmation shall be provided that each batch meets pre-established specifications