



Institut luxembourgeois de la normalisation  
de l'accréditation, de la sécurité et qualité  
des produits et services

## ILNAS-EN 17647:2022

### **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

07/2022



## National Foreword

This European Standard EN 17647:2022 was adopted as Luxembourgish Standard ILNAS-EN 17647:2022.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

<https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html>

### **THIS PUBLICATION IS COPYRIGHT PROTECTED**

Nothing from this publication may be reproduced or utilized in any form or by any mean - electronic, mechanical, photocopying or any other data carries without prior permission!

EUROPEAN STANDARD ILNAS-EN 17647:2022 **EN 17647**  
NORME EUROPÉENNE  
EUROPÄISCHE NORM July 2022

---

ICS 65.160

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 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.

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, Turkey 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**

---

<b>Contents</b>	<b>Page</b>
<b>European foreword .....</b>	<b>3</b>
<b>Introduction .....</b>	<b>4</b>
<b>1 Scope.....</b>	<b>5</b>
<b>2 Normative references.....</b>	<b>5</b>
<b>3 Terms and definitions .....</b>	<b>5</b>
<b>4 E-liquid manufacturing.....</b>	<b>7</b>
4.1 Quality system.....	7
4.2 Process.....	7
4.2.1 Manufacturing facilities.....	7
4.2.2 Production equipment.....	7
4.2.3 Process control .....	7
4.2.4 Product and production specification.....	9
4.2.5 Batch traceability.....	9
4.2.6 Maintenance and sanitation.....	10
4.2.7 Qualification of material and suppliers.....	10
4.2.8 Corrective and preventive actions.....	11
4.2.9 Recalls and withdrawal (serious quality incident management) .....	11
4.2.10 Transportation, storage, and distribution.....	12
<b>Bibliography .....</b>	<b>13</b>

## 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.

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.

## 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<sup>1</sup> and FprEN 17648<sup>2</sup> 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

---

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

<sup>2</sup> 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.