

STN	Všeobecné zásady výroby, plnenia a držania náplní do elektronických cigariet pre predplnené nádoby alebo výrobky	STN EN 17647 56 9585
------------	---	--

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/22

Obsahuje: EN 17647:2022

135650

EUROPEAN STANDARD

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

EN 17647:2022 (E)

Contents		Page
European foreword		3
Introduction		4
1	Scope.....	5
2	Normative references.....	5
3	Terms and definitions.....	5
4	E-liquid manufacturing.....	7
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
Bibliography		13

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.

EN 17647:2022 (E)**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 17633¹ and FprEN 17648² are intended to be used in conjunction with this document.

2 Normative references

There are no normative references in this document.

koniec náhľadu – text ďalej pokračuje v platenej verzii STN

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.