

General Prerequisites for Traditional Cigarettes Alternatives

Part One: Electronic Cigarettes – Electronic Liquid

1. SCOPE

This Egyptian standard is concerned with the basic requirements and standard of the liquids used in Electronic Cigarettes (E-Cigarettes), in addition to the containers which contain these liquids.

2. DEFINITIONS

2.1. Electronic Cigarettes (E-Cigarettes):

A product that provides the smoker with an aerosol to inhale, by electrically heating a liquid (e-liquid) that resides within the product or within a prefilled or a refillable cartridge (tank). Unlike other tobacco products, E- Cigarettes do not contain any tobacco.

2.2. Electronic Liquid (E-Liquid):

A compound liquid of propylene glycol (PG), glycerol, and nicotine mixed with concentrated flavors. The liquid is usually kept in the container of the e-cigarette. The smoker inhales the aerosol resulting from electrically heating the liquid. E-liquids may be free of nicotine.

2.3. Refilling Container:

The container which contains the e-liquid, used to refill the e-cigarette.

2.4. Nicotine:

An alkaloid that may occur in every part of the tobacco plant. Usually, tissues containing the highest concentration levels are the leaves.

2.5. Cartridge (tank):

The part that contains the e-liquid and it is put directly into the e-cigarette. The cartridge is usually replaced when the e-liquid is used up.

3. BASIC REQUIREMENTS

3.1. It is not permissible for e-liquids to be imported, exported, produced (provision 2.2), distributed, and/or sold in the market, unless they satisfy the standard and legislation set forth by the Ministry of Health in this regard.

- 3.2.** All containers used to be refilled with the e-liquid (provision 2.3) must be free of all manufacturing defects (cracks) or any defects otherwise that may lead to leakage.
- 3.3.** All containers used, and which are mentioned in provision 3.2, must be sealed and kept inside a suitable packaging (provision 4), provided that packaging and wrapping are compatible with the standard set forth in provision (7.2.1).
- 3.4.** If the e-liquid is to contain nicotine, nicotine concentration must not exceed 30 milligrams per milliliter.
- 3.5.** The size of the e-liquid refilling container (provision 2.2) must not exceed 10 milliliters for the e-cigarette refilling containers, and 2 milliliters for the single-use cartridge (tank) containing the e-liquid.
- 3.6.** The e-liquid must not contain any additives, like vitamins or anything otherwise that may give the impression that the solution has health benefits.
- 3.7.** Adding caffeine, taurine, and/or any other stimulant that is related to energy and vitality, is not allowed.
- 3.8.** Adding any substances to color the generated aerosol, is not allowed.
- 3.9.** Manufacturing e-liquids may not involve except highly pure ingredients (which is the minimum for foods), i.e. food grade.
- 3.10.** Minimum purity of each of propylene glycol (PG) and glycerol (plant based) must be at least 99.5%.
- 3.11.** Flavorings must be food grade in accordance with the legislations in that regard.
- 3.12.** Minimum purity of nicotine must be at least 99%.

4. PACKAGES AND INFORMATION

- 4.1.** The e-liquid shall be kept in containers (provision 2.3) that are suitable, shatterproof, anti-leaking, and can maintain the quality and properties of the e-liquid.
- 4.2.** Containers mentioned in provision 2.3 must be manufactured of safe material and must be appropriate for the purpose of usage, in accordance with the legislations in this regard, and which are concerned with packing material used in manufacturing food containers.
- 4.3.** Packages containing the containers must have the following information in Arabic, and may be in other foreign languages in addition to Arabic language, in clear readable text that is indelible and unerasable:

- 4.3.1. Product nature (e-liquid).
- 4.3.2. The brand name.
- 4.3.3. The product name and its trademark.
- 4.3.4. The importer, the importer address, and the country of origin if the product was imported.
- 4.3.5. The phrase “Made in Egypt” in case of a locally produced product.
- 4.3.6. The nicotine concentration (milligrams per milliliter) if nicotine is present.
- 4.3.7. The liquid size measured in milliliters, and a statement with the ingredients sorted in a descending order by weight.
- 4.3.8. The phrase “Store in a cool dry place away from direct sunlight.”
- 4.3.9. The phrase “Keep out of reach of children.”
- 4.3.10. Must not contain any claim such as “Helps reduce the frequency of smoking.”
- 4.3.11. The phrase “Cannot be sold to any person under the age of 18 years.”
- 4.3.12. The package must display the graphic health warning labels issued in this regard.
- 4.3.13. The banderole tax stamp on the package.
- 4.3.14. The package must include inner information leaflet with health and environmental warnings, How to Use, storing conditions, method of disposal, and how to safely use the product, like; Do not let the product touch the skin, do not swallow the e-liquid, ...etc.

5. METHODS OF EXAMINATION AND TESTING

5.1. The Method of Determining Glycerin

Egyptian Standards number 8160/2018, regarding “Determination of Glycerin, Propylene, Water, and Nicotine in E-cigarettes, Using Gas Chromatograph (GC) Analyzer.”

5.2. The Method of Determining 1, 2- Propylene Glycol

Egyptian Standards number 8161/2018, regarding “Determination of 1, 2- Propylene Glycol and Glycerin in Tobacco and Tobacco Products, Using Gas Chromatograph (GC) Analyzer.”

5.3. The Method of Discovering Caffeine

Egyptian Standards number 6944/2009, regarding “Determination of Nicotine in Tobacco and Tobacco Products (Chemical Method).”

6. TECHNICAL TERMS

Nicotine	النيكوتين
E-liquid	السائل الإلكتروني
Cartridge (tank)	حاوية إعادة التعبئة
Electronic Cigarette	السيجارة الإلكترونية

7. REFERENCES

7.1. Main References

7.1.1. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC Text with EEA.

7.1.2. FNOR-D90-300-1: Requirements and text methods for electronic cigarettes.

7.1.3. CORESTA RECOMMENDED METHOD N° 60

DETERMINATION OF 1, 2 – PROPYLENE GLYCOL AND GLYCEROL IN TOBACCO AND TOBACCO PRODUCTS BY GAS CHROMATOGRAPHY.

7.1.4. CORESTA Recommended Method

No. 84 DETERMINATION OF GLYCERIN, PROPYLENE GLYCOL, WATER, AND NICOTINE IN THE AEROSOL OF E-CIGARETTES BY GAS CHROMATOGRAPHY ANALYSIS.

7.2. Complementary References

7.2.1. Egyptian Standard number 5504/2006, “Child Tamper-proof Packaging – Requirements and Test Methods for Resealable Packages Designated as Resistant to Opening by Children.”

7.2.2. Egyptian Standard number 8160/2018 regarding “Determination of Glycerin, Propylene Glycol, Water, and Nicotine in E-cigarettes by Gas Chromatography Analyzer.”