

Technical Regulation No: SFDA.FD 5005:2020

Electronic Nicotine Delivery Systems

Disclaimer: The English version is a translation of the original in Arabic for information purposes only. In case of discrepancy, the Arabic original will prevail.

Preamble

Saudi Food & Drug Authority is an independent agency mandated with regulating and controlling locally produced and imported food, drug and medical devices and setting their technical regulations and standards. SFDA.FD5005:2020 “*E-liquids and Heated Tobacco in Electronic Nicotine Delivery Systems*” is a draft regulation updated by the SFDA Food Sector after reviewing relevant technical documents. It was adopted on 30/11/1441 AD (corresponding to July 11,200) by SFDA CEO decision No. (11/7-18-1440).

E-Liquids and Heated Tobacco in Electronic Systems for Smoking

1- Domain and Scope of Application:

This standard regulation shall lay down the requirements and conditions for E-liquids and heated tobacco products used in Electronic Nicotine Delivery Systems (ENDS).

2- Complementary References

2.1 SASO NO (172-19-04-03) “Technical Regulation for Electronic Devices Used in Electronic Smoking Systems.

3- Definitions

3.1 **Tobacco:** processed and unprocessed leaves and other natural parts of the tobacco plant, including formulated tobacco.

3.2 **Nicotine:** Nicotinic alkaloids.

3.3 **Special Flavor:** a taste or smell perceived prior to or after consuming the product.

3.4 **E-Liquid:** Liquid combination or gel that may contain Nicotine and some additives.

3.5 **Heated Tobacco:** Processed or unprocessed tobacco in the form of coils, powder, or granules inside capsules used with heating with no burning.

3.6 **Product:** E-liquid or heated tobacco.

3.7 **Emissions:** substances released when the product is used.

3.8 **Health Warning:** a warning statement shown on the label, describing potential risks associated with the product.

3.9 **Package:** the unit/units of wrapping, in which the product is contained and offered for sale.

3.10 **Outer Packaging:** any surface of the package distinctively discernable before the container is opened, apart from the transparent sheet (cellophane).

4- General Requirements:

4.1. All the requirements outlined in the *Technical regulation for Electronic devices Used in Electronic Smoking Systems* stated under item 2.1. shall be satisfied.

4.2. The filter, paper, capsules and other related components shall not contain tobacco or other substances which are derived from tobacco or may increase emissions.

4.3. The product shall not contain the following:

4.3.1. Vitamins or other additives which may create an impression that it has health benefits or reduces health risks.

4.3.2. Caffeine, taurine or other additives or stimulants that are associated with energy and vitality.

4.3.3. Additives that give coloring effects to any emissions.

4.3.4. Additives with CMR properties or that can affect CMR properties (Carcinogenic, mutagenic or toxic for reproduction)

5- E-Liquid Requirements:

- 5.1. The containers shall be hermetically sealed, child-resistant, shatterproof, impervious and waterproof when used or refilled.
- 5.2. Only fruit, tobacco, menthol, or a combination of these flavourings are permitted in E-liquids. Other flavorings such as cocoa, vanilla, coffee, tea, condiments and sweets, are strictly prohibited.
- 5.3. E-liquid shall be manufactured using only ingredients of high purity.
- 5.4. It shall contain nicotine at a maximum limit of 20 mg/ml.
- 5.5. The external refilling tank shall not contain more than 30 ml of E-liquid per package.
- 5.6. Each pod shall not contain more than 2 ml of E-liquid.
- 5.7. The level of toxic solvents for both ethylene glycol and diethylene glycol shall not be greater than 0.1%.
- 5.8. The maximum microbiological limits shall be according to the following:

Microbiological testing	Maximum limits
Total aerobic microbial count	10 ² CFU/ml or CFU/g
Total combined yeasts/mould count	10 ¹ CFU/ml or CFU/g
Staphylococcus aureus	Should be absent
Pseudomonas aeruginosa	Should be absent
Bile-tolerant gram negative bacteria (1 g or 1 ml)	Should be absent

5.9 The maximum limits for heavy metals shall be according to the following:

Metal	Maximum limit (µg/g)
Cadmium	0.2
Lead	0.5
Arsenic	0.2
Mercury	0.1
Chromium	0.3
Nickel	0.5
Tin	6
Copper	3

6- Illustrative information and health warning:

1.1. The information on the label shall not contain the following:

1.1.1. Any indication or suggestion that the product is less harmful than other tobacco products or aims to reduce harmful effects of smoke, or has vitalizing, energizing, healing, rejuvenating, natural or organic properties, or has other health or lifestyle benefits.

1.1.2. Any advertisement or promotional offers

1.2. The outer packaging shall contain a health warning that meets the following criteria:

1.2.1. The texts of the warning statement shall be in black, Helvetic Bold against a white background and in large font covering the entire area that is reserved for it, and to be visibly prominent on both sides (back and front) and surrounded by a 1 millimeter-wide black border.

1.2.2. It shall cover at least 30 % of the entire (including the borders) surfaces pointed out above in 6.2.1.

1.2.3 The warning statement shall read as the following:

1.2.3.1. For heated tobacco, it shall read: “This product damages your health and contains addiction-causing nicotine.”

1.2.3.2. For nicotine-containing E-liquids, it shall read: “This product damages your health and contains addiction-causing nicotine.”

1.2.3.3. For nicotine-free E-liquids, it shall read: “This product damages your health and it is not recommended to be used”.

1.3. The outer packaging shall contain the following information:

1.3.1 Arabic and/or English band name (trademark), variant or flavor (if applicable).

1.3.2 Production date (month/year).

1.3.3 Country of origin.

1.3.4 Name of manufacturer and/or importer.

1.3.5 Nicotine concentrations if applicable (in mg/ml, or mg/cigarette).

1.3.6 Measurement marks, size and weight.

Technical Terms

Heated Tobacco	التبغ المعد للتسخين
E-Liquid	السائل الإلكتروني
Pod	الوحدة المغلقة ذات الاستخدام الواحد
Refill Container	عبوة إعادة التعبئة الخارجية
Health Warning	التحذير الصحي
Electronic Systems for Smoking	النظم الإلكترونية للتدخين

References:

Tobacco Products Directive 2014/14/EU (TPD)	التنظيم الأوروبي لمنتجات التبغ
European Pharmacopoeia	دستور الأدوية الأوروبي.
US Pharmacopoeia	دستور الأدوية الأمريكي.