

Overview of SANS 2094:2024 – 20 Pages with Annexure A

Development and Approval

- Prepared by SABS/TC 2112: Vaping Products, adhering to WTO/TBT Annex 3 standards.
- Approved for publication in September 2024.

Purpose

- Provides definitions, guidelines, and best practices for electronic vaping products (e-cigarettes, ENDS, ENNDS).
- Aims to reduce consumer risks via test methods and standards.

Key References

- South African legislation:
 - Occupational Health and Safety Act (1993)
 - Hazardous Chemical Agents Regulations (2021)
 - Consumer Protection Act (2008)
 - Hazardous Substances Act (1973)

Product Scope

- Applies to all electronic vaping devices (current and future).
- Covers nicotine and non-nicotine delivery systems, e-liquids, and components.

Guidelines

- Includes methods for risk mitigation and consumer safety.
- Recommends further standardization for unaddressed methods.

Compliance Note

- Adherence to this standard does not exempt from legal obligations.
- Annex A forms an integral part of the standard.

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Normative References (Page 3 & 4)

•Packaging and Materials

- EN 862: Child-resistant packaging – Testing non-reclosable packages **for non-pharma products**.
- EN 1186: Plastics in contact with foodstuffs.
- EN 14401: Effectiveness of closures for rigid plastic containers.

•Electromagnetic Compatibility

- EN 55014-1 & EN 55014-2: Requirements for household appliances and electronic tools.

•Battery Safety

- IEC 62680-3: Standards for prismatic and cylindrical lithium secondary cells.

Hazardous Substances: IEC 63000 – Restriction on hazardous substances in products.

- **Child Safety:** ISO 8317 – Child-resistant packaging for reclosable packages.

•Testing and Labelling

- **E-Liquid Testing:** ISO 20714 – Nicotine and ingredient analysis in e-liquids.
- **Labelling:** ISO 28219 – Barcode and 2D symbol marking.

•Electrical and EMC Compliance

- **General Safety:** SANS/IEC 60335-1 – Household appliance standards.
- **EMC Limits:** SANS/IEC 61000-3-2 & 61000-3-3 – Current emissions and voltage fluctuation limits.

•Battery and Electromagnetic Fields

- **Battery Safety:** SANS/IEC 61960 – Lithium secondary cells for portable applications.
- **Human Exposure:** SANS/IEC 62233 – Measurement of electromagnetic fields.

•User Guidance

- SANS/IEC 82079-1 – Structuring and presentation of instructions for use.

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Terms and Definitions (Page 4 & 5)

Electronic Cigarette (e-Cigarette)

- A device for human use that vaporizes a liquid to create an aerosol inhaled by the user.
- Includes products such as **ENDS**, **e-cigars**, **e-shisha**, **e-pipes**, and other vaping products.

Product Variants

- Devices can be:
 - **Single-piece** or **modular, multi-component** designs.
 - **Disposable**, **rechargeable**, or **refillable**.
 - **Proprietary cartridges** (pre-filled liquid) replaceable in some designs.

Key Distinction

- Unlike **tobacco products** (e.g., heated tobacco), e-cigarettes do **not contain tobacco**.

e-Liquid

- Liquid or gel (may contain nicotine) transformed into an aerosol for inhalation.

Key Components

- **e-Liquid Container:** Holds e-liquid for filling reservoirs.
- **Power Unit:** Supplies power to the atomizer (includes battery and controls).
- **e-Liquid Reservoir:** Stores and supplies e-liquid to the atomizer (includes tanks and refillable pods).
- **Cartridge/Pod:** Pre-filled e-liquid container for direct loading into devices.
- **Filling Mechanism:** Part of the reservoir for refilling and securing e-liquid.
- **Atomizer:** Device transforming e-liquid into an aerosol (includes atomizer head).

User Interaction

- **Mouthpiece:** Contact point for the user to draw aerosol (also called drip tip).

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Principle of electronic vaping products and their components and the general requirements thereof (Page 5-13)

Common Components Across Designs

- a) **Power Unit:** Supplies energy to the system.
- b) **Atomizer:** Generates the aerosol from e-liquid.
- c) **Cartridge/Pod/Reservoir:** Stores the e-liquid (tank or pre-filled).
- d) **Mouthpiece:** Enables users to draw aerosol from the device.

Key Insight

•Despite diverse designs, these components are universal to all electronic vaping products.

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Throughout pages 5 and 13, each respective item in the content is expanded upon with the general restrictions and standardised references to relevant specifications from the Normative References ranging from manufacturing and composition of devices (*refers to Annex A, summarised later*), packaging and labelling, e-liquid composition and manufacturing, warning labels and nicotine content.

Overview of SANS 2094:2024 cont.

Principle of electronic vaping products and their components and the general requirements thereof (Nicotine Content Allergens and Ingredients)

Risk Mitigation

- Manufacturers and importers should limit **home blending** and **e-liquid customization** by adhering to nicotine standards.
- High-concentration liquid or powdered nicotine for industrial use should not be accessible to consumers.

Nicotine Standards

- Maximum Concentration:** Nicotine content should not exceed **35 mg/ml**.
- Pharmaceutical Grade:** Nicotine must meet pharmaceutical-grade standards with supporting **certificates of analysis**.
- Measurement Compliance:** Nicotine concentration must be tested following **ISO 20714** methods.

Potential common allergens/sensitizers are listed within the standards. Most importantly, ingredients that are on the Negative list can be seen on the right.

8.1.4.6 Negative ingredients list (to be considered such as in the European Union Tobacco Products Directive (EU TPD), where the negative list is) based on toxicological properties – prohibits use of ingredients that are CMR (i.e. carcinogenic, mutagenic or reprotoxic).

8.1.4.7 Toxicological risk assessment shall be held by the manufacturer or importer to demonstrate the ingredients used in the e-liquid are safe for their intended purpose.

8.1.4.8 All consumable ingredients shall be accompanied by appropriate relevant certificates of analysis demonstrating compliance with purity requirement.

8.1.5 Ingredients for E-liquids (Negative list)

Substances given in table 2 should not be added to e-liquids.

Table 2 — Substances not to be added to vaping products without scientific justification

1	2
Substances	Comments
Carcinogenic, mutagenic or reproductive toxicants (CMRs) (or both)	E-liquid should not contain ingredients/substances classified as CMRs.
Respiratory sensitizers	E-liquid should not contain ingredients/substances classified as respiratory sensitizers.
Diacetyl (CAS 431-03-8) and Pentane 2,3 dione, CAS 600-14-6	Permissible exposure levels should be referred to in relevant regulatory and scientific literature.
Diethylene glycol (CAS 111-46-6) Ethylene glycol (CAS 107-21-1)	These should not be added as substances in e-liquids but may be present as contaminants of glycerol and propylene glycol at a maximum level of 0,1%
Formaldehyde (CAS 50-00-0), Acetaldehyde (CAS 75-07-0), and Acrolein (CAS 107-08-8)	These should not be added as ingredients to e-liquids but might be present. If they are present, they should not be present above toxicologically supportable levels, as identified by toxicological risk assessments, including preservatives liable to release formaldehyde.
Heavy metals: Cadmium (CAS 7440-43-9), Chromium (CAS 7440-47-3), Iron (CAS 743989-6), Lead (CAS 7439-92-1), Mercury (CAS 7439-97-6), and Nickel (CAS 7440-02-0))	Metals should not be added to e-liquids as ingredients but might be present. If they are present, they should not be present above toxicologically supportable levels, identified by toxicological risk assessments. Low levels of lead and nickel levels can be analysed using ICP technology.
Vitamin E acetate	—
Mineral oils, vegetable oils or animal fats as carriers or solvents.	—
Ingredients classified as psychotropic, except nicotine.	—

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Principle of electronic vaping products and their components and the general requirements thereof (Page 16, Annex A. Annex A refers to a Drop Test)

Applicability

- Applies to **e-liquid containers, cartridges, and assembled vaping devices.**
- Not for glass or glass-combination samples.

Test Conditions

- Test Surface:** Concrete.
- Pre-conditioning:** Temperature equilibrium between **15°C to 25°C** for at least **2 hours**.

Test Procedure

- Drop **3 times** from **1,000 mm** in three orientations:
 - **Horizontal (0°)**
 - **Vertical (90°), mouthpiece down**
 - **Angled (45°), mouthpiece down**

Failure Criteria

- Breakage:** Obvious fracture = test failure.
- Leakage:** If leakage is visible after **1 hour** (on paper tissue) = test failure.

Bibliography of SANS 2094:2024

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Standards

SANS 9001/ISO 9001, *Quality management systems – Requirements.*

Other publications

European Union Tobacco Products Directive (EU TPD).

Key Sections of SANS 2094:2024

8.1.2 Warnings

8.1.2.1 Every outside package of either e-liquid containers or pre-filled cartridges, pods, reservoirs shall have a visible warning as: 'This product contains nicotine and is addictive', unless it does not contain nicotine, as well as a 'No Sale to Under 18' stamp.

8.1.2.2 Any potential outer packaging in which the product is sold to consumers, as well as the product label and product information, shall carry the statement: "Keep Out of Reach of **Children**"

8.1.2.3 The company name should be furnished with details of the key ingredients used in the product once the product is launched into the South African market.

8.1.2.4 The packaging and labelling shall clearly advise users to dispose of the product responsibly.

8.1.2.5 Product packaging for e-liquid containing products and devices shall carry a manufacturing date or expiry date. The information should be permanently printed or marked on the e-liquid containers.

8.1.2.6 Storage conditions should be included on the packaging to ensure the correct stability of the ingredients and avoid any untoward or adverse effects on the product.

8.1.2.7 To further ensure safety to the users, allergic substances and constituents listed in table 1 that may be present in the finished product shall be clearly stated on the outer packaging or the instruction manual to inform consumers or users of potential intolerances to the ingredients.

8.1.2.8 E-liquids, Safety Data Sheets (SDSs) and product labelling should comply with the relevant national legislation (see foreword).

5.3 Child resistance

5.3.1 The e-liquid container shall be child-resistant whereas cartridges and pods are considered as already child resistant as access to the e-liquid is prevented.

5.3.2 The e-liquid container shall be child-resistant and in accordance with EN 862 or ISO 8317.

5.4 Tamper evident

The seal of the e-liquid container or any prefilled cartridges or prefilled reservoirs shall be tamper evident such that a user can visually discriminate whether the e-liquid container has been opened since manufacture.

6 Labelling

NOTE Labelling is considered as information that appears on product packaging or is applied to the product itself (or both). In the case that it is applied to the product it would normally be removable.

6.1.2 Traceability

Traceability is a fundamental requirement for consumers, the enforcing authorities (Government), and the manufacturers. Traceability of vaping products including e-liquids is mandatory, and the technology solution should comprise the following key elements:

- a) Authentication – covert or overt that enables customers and law enforcement to verify the authenticity of our products;
- b) Traceability – ability for law enforcement to trace the source of products and for consumers to determine where to purchase the product from legitimate retail locations;
- c) Tamper resistance – product safety standards that prevent inadvertent issues and non-genuine components/ingredients from being introduced and consumed using devices
 - 1) All vaping products manufactured in or imported into South Africa shall ensure clear traceability mechanisms.
 - 2) 'Know your customer' controls with suppliers: Suppliers of key inputs shall ensure the integrity of their materials as well as their supply chains. On request, these should be readily available to enforcing authorities.

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4.3.3 Charging unit

Charging circuitry shall be designed in compliance with EN 62133. In addition, electronic vaping devices and charging units utilising a USB socket for charging shall be in compliance with IEC 62680-3.

4.4 Atomizer

4.4.1 Where part of the atomizer comprises components that come into contact with e-liquid, the materials used shall

- a) be capable of having the insulating properties required at the foreseeable voltages and currents used,
- b) be capable of resisting the maximum heater temperature or maximum heater power the atomizer will operate to,
- c) be safe under conditions of intended use and reasonably foreseeable misuse, and
- d) not be of adverse influence on the microbiological safety of e-liquid.

4.4.2 Atomizers shall not transfer their constituents to the content of e-liquid in quantities that change the composition of the e-liquid or the aerosol and thereby significantly increase the risk for the consumer. There may be an unavoidable transfer of low levels of metals from the heating element during long-term storage and operation, but these shall be as low as reasonably practicable and shall not significantly increase levels of risk to the consumer.