

PAS 54115:2015

Vaping products, including electronic cigarettes, e-liquids, e-shisha and directly-related products – Manufacture, importation, testing and labelling – Guide



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Foreword

This PAS was sponsored by the Electronic Cigarette Industry Trade Association, ECITA (EU) Ltd. Its development was facilitated by BSI Standards Limited and it was published under licence from The British Standards Institution. It came into effect on 31 July 2015.

Acknowledgement is given to the following organizations that were involved in the development of this PAS as members of the steering group:

- Electronic Cigarette Consumer Association of the United Kingdom (ECCA UK)
- Knowledge Action Change (KACChange)
- New Nicotine Alliance
- Nicoventures
- Totally Wicked Ltd
- Trading Standards Institute

Acknowledgement is also given to the members of a wider review panel who were consulted in the development of this PAS.

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This PAS is not to be regarded as a British Standard. It will be withdrawn upon publication of its content in, or as, a British Standard.

The PAS process enables a guide to be rapidly developed in order to fulfil an immediate need in industry. A PAS can be considered for further development as a British Standard, or constitute part of the UK route to the development of a European or International standard.

Use of this document

As a guide, this PAS takes the form of guidance and recommendations. It should not be quoted as if it were a specification or a code of practice and claims of compliance cannot be made to it.

It has been assumed in the preparation of this PAS that the execution of its provisions will be entrusted to appropriately qualified and experienced people, for whose use it has been produced.

Presentational conventions

The guidance in this standard is presented in roman (i.e. upright) type. Its recommendations are expressed in sentences in which the principal auxiliary verb is "should".

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

Where words have alternative spellings, the preferred spelling of the Shorter Oxford English Dictionary is used (e.g. "organization" rather than "organisation").

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with this PAS cannot confer immunity from legal obligations.

Particular attention is drawn to the following specific regulations:

- General Product Safety Directive 2001/83/EC (as amended in 2004) [1]
- Low Voltage Directive 2006/95/EC [2]
- Electromagnetic Compatibility Directive 2004/108/EC [3]
- Restriction of Hazardous Substances Directive 2011/65/EU [4]
- Classification Labelling and Packaging Regulation (EC) No. 1272/2008 [5]
- Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No. 1907/2006 [6]
- Waste Electrical and Electronic Equipment Directive 2012/19/EU [7]
- Batteries and Accumulators and Waste Batteries and Accumulators (Battery) Directive 2006/66/EC [8]
- Radio Equipment and Telecommunications Terminal Equipment Directive 1999/5/EC [9]
- Medicinal Products Directive 2001/83/EC [10]
- Tobacco Products Directive 2014/40/EU [11]
- Control of Poisons and Explosives Precursors Regulations 2015 [12]
- Poisons Act 1972 [13]
- Control of Substances Hazardous to Health Regulations 2002 [14]
- Personal Protective Equipment (PPE) At Work Regulations 2002 [15]
- Health and Safety (First-Aid) Regulations 1981 [16]
- Health and Safety At Work etc. Act 1974 [17]

Attention is also drawn to the Committee of Advertising Practice and Committee of Broadcasting Practice's *New rules for the marketing of e-cigarettes* (Oct 2014) [18] and the ECITA Industry Standard of Excellence (ISE), Public Edition [19], available from www.ecita.org.uk.

Introduction

Background

Electronic cigarettes (e-cigs) and other vaping products (VP) are a rapidly growing market sector. It is prudent, therefore, to provide guidance on manufacturing, importing, labelling and marketing practices, to highlight the importance of safety and quality for consumers who wish to have access to VP.

The approach taken for this guidance

This guidance offers good practice solutions which are achievable and enforceable, with the minimum burden placed both on businesses operating in the sector, and on government enforcement agencies.

The guidance outlined in this PAS is designed to help provide information and recommendations on product safety and quality to meet consumer needs, minimize negative impacts on the environment, enable swift product innovation, and maintain technological neutrality.

This PAS covers:

- purity of e-liquid ingredients in manufacture;
- contaminants arising from device materials and potential emissions from device operation;
- electrical safety;
- metals and carbonyls in emissions.

NOTE 1 This PAS maintains technological neutrality through its recommendations for producers. This means that safety and quality guidance is not technology-specific, but focussed on the outcome of the test/assessment. This is important so as not to disadvantage products with particular technologies compared to other products, as well as to future-proof the PAS, insofar as this is possible for emerging technologies.

Recent regulatory assessment of toxicological data on nicotine [2, 3] has determined that e-liquids containing up to 20% w/v nicotine concentration do not require a hazard classification for acute oral and/or dermal toxicity in accordance with the Classification Labelling and Packaging Regulation (EC) No. 172/2008 (CLP) [5].

NOTE 2 The harmonized classification of nicotine under CLP is currently under review at the European level, so this might change after publication of this PAS.

Why is guidance on safety and quality necessary?

Safety and quality guidance is necessary to provide minimum expectations to producers and reassurance both to regulators and the public that product safety and quality is maintained across batches and can be reliably demonstrated with documentary evidence.

How can guidance be created for products with such diversity?

Guidance needs to be relevant to all the various product types currently available, as well as to those that will be developed. Not all elements of this guide will apply to every product, but the definitions can be used to identify guidance relevant to specific products, or parts of products, within this diverse sector.

It is very important that guidance covers vaping products without nicotine (VPWNs), as well as VPs containing nicotine, because safety and quality concerns are equally relevant to VPs which do not contain nicotine, since all such products are designed for inhalation.

What about consumers mixing e-liquid for themselves?

E-liquid is sold in different forms for different sectors of the market. For the DIY market, base liquids (with and/or without nicotine) are provided, usually together with flavour concentrates for the consumer to blend for themselves. The toxicity of the nicotine-containing base liquid can be mitigated by providing detailed instructions for handling and dilution.

NOTE 3 Attention is drawn to CLP [5].

How does this guide help?

In order for producers and distributors of VP to be able to provide reassurance to the public, they need to know how their products are made, what goes into them, and what emissions are produced during their use. The guidance in this PAS is provided to assist producers and distributors in assessing their products for these factors, so that their documentary evidence will be robust.

1 Scope

This PAS gives guidance for the manufacture, importation, labelling, marketing and sale of vaping products (VP) including electronic cigarettes, e-shisha, DIY e-liquid mixing kits, and directly related products.

The PAS also gives guidance focussing on the purity of e-liquid ingredients in manufacture, contaminants arising from device materials and potential emissions from device operation, electrical safety, and metals and carbonyls in emissions. The PAS describes a test solution-liquid, and an outline for the toxicological and chemical analysis of emissions.

The PAS also gives guidance for the safety of batteries and chargers.

The PAS refers to existing safety guidance already in place which are relevant to this sector.

The PAS is applicable to producers and distributors of VP in the UK, and forms a guide for commercial operations in this sector.

The PAS is also applicable to laboratories and testing houses engaged in, or planning to be engaged in, the testing of VP.

This PAS is not intended to cover those VP which are licensed as medicinal products or medical devices. It is not intended to cover "heat not burn" or other tobacco products. It does not cover wireless communication features which may be built in to vaping devices, but does cover the vaping products themselves. It also does not cover products which can be used in or as VP, but which are sold for other purposes, e.g. food flavourings sold in supermarkets.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS EN 862, *Packaging – Child-resistant packaging – Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products*

BS EN 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*

BS EN ISO 8317, *Child-resistant packaging – Requirements and testing procedures for reclosable packages*

European Pharmacopoeia, *Purified water* Monograph 0018

European Pharmacopoeia, *Nicotine* Monograph 1452

European Pharmacopoeia, *Glycerol* Monograph 0496

European Pharmacopoeia, *Propylene glycol* Monograph 0430

United States Pharmacopeia, *Propylene Glycol* Monograph

United States Pharmacopeia, *Purified water* Monograph

United States Pharmacopeia, *Nicotine* Monograph

United States Pharmacopeia, *Glycerin* Monograph