



# Chemical safety of vapes

## Guidance on assimilated Regulation (EC) No 1272/2008 (GB CLP), as it applies to vaping products

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Chartered Trading Standards Institute, 1 Sylvan Way,  
Southfields Business Park,  
Basildon SS15 6TH  
[www.tradingstandards.uk](http://www.tradingstandards.uk)  
01268 582 200

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## INTRODUCTION

### The legal background

To fully understand this guidance, it is important to note the difference between the United Kingdom and Great Britain:

- UK: England, Scotland, Wales and Northern Ireland
- GB: England, Scotland and Wales

In this guide, the words ‘must’ or ‘must not’ are used where there is a legal requirement to do (or not do) something. The word ‘should’ is used where there is established legal guidance or best practice that is likely to help you avoid breaking the law.

### Classification, labelling and packaging of substances and mixtures

Great Britain adopted the United Nations’ Globally Harmonised System of Classification and Labelling of Chemicals via assimilated Regulation (EC) No 1272/2008 *on classification, labelling and packaging of substances and mixtures*. Post-Brexit, it is generally known as GB CLP and covers risks to health and to the environment.

In GB CLP, “‘supplier’ means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture”.

If you are a manufacturer or importer, you are responsible for classifying hazardous chemicals, substances and mixtures before they are placed on the market. You are also responsible for packaging and labelling chemicals, substances

and mixtures in line with GB CLP. This includes those suppliers that do not carry out reformulation but are involved in repacking or relabelling.

A retailer is termed a ‘distributor’ under GB CLP. As a distributor, you must ensure that vaping products are properly labelled in accordance with the requirements of GB CLP before you agree to purchase them.

## GB CLP

### How the Regulation applies to vaping products

### Chemical hazards and vapes

Product regulation seeks to manage risk in a number of ways, and generally follows the hierarchy of risk management.

#### Stage 1

Elimination of product hazards (features of the product that have the potential to cause harm). If hazards are eliminated, they have no risk associated with them.

Some hazards are necessary for product functionality or cannot be eliminated; when this is the case, we go to stage 2.

#### Stage 2

Mitigation of product risk. This is where the product is designed in such a way that either the probability of the hazard causing harm is reduced and/or the severity of harm is reduced.

It is sometimes impossible to adequately mitigate risk; then, and only then, does stage 3 apply.

#### Stage 3

Warning users (and others) of the hazards that are present, and outlining the precautions necessary to avoid harm.

Vaping products often contain nicotine, which is a hazardous substance. Elimination is not possible

whilst retaining product functionality; therefore, the risk must be mitigated and warnings provided.

GB CLP provides the framework for the mitigation of risk and warning of residual hazards.

## Overview of the Regulation

As mentioned in the introduction, GB CLP follows the UN’s Globally Harmonised System of Classification and Labelling of Chemicals. This system sets out:

- criteria for classifying chemicals according to their health, environmental and physical hazards
- hazard communication requirements for labelling and safety data sheets

The classification system is undertaken by the scientific community through specific institutions, and this facilitates the necessary packaging and labelling requirements to ensure users (in this case, consumers) are adequately informed about hazards and the steps they should take to avoid harm.

GB CLP provides a framework for the assessment of risk and sets out the appropriate control measures for the substances or mixtures that are present in products. It sets out obligations on suppliers when the products are placed in the supply chain.

Firstly, suppliers must determine whether their products include anything containing substances that are classified as hazardous, and then label and package them as laid down in the Regulation.

Nicotine is a substance that is classified as hazardous and, therefore, the necessary control measures must be used for product labelling and packaging.

Packaging of products containing classified chemicals must have a label

providing the following in respect of the substance or mixture:

- name, address and telephone number of supplier
- the nominal quantity of the substance or mixture in the package (consumer products only)
- product identifiers, such as ‘nicotine’
- hazard pictograms, where applicable
- the relevant signal word, where applicable
- precautionary statements, where applicable
- supplementary information, where applicable

The specific pictogram, signal word, hazard and precautionary statements reflect the hazard classification assigned to the substance.

### Nicotine classification

Under GB CLP, the classification of e-liquid mixtures depends on their nicotine content. It should be noted that this is the usual classification for the different strength e-liquids, but advice should always be sought from a competent chemist when determining the appropriate classification of e-liquids, as additives and variations in density can change the classifications detailed below:

- over 1.7% of nicotine is classified as ‘Toxic’
- between 0.49% and 1.7% is classified as ‘Harmful’
- under 0.49% of nicotine is not classified

20 mg/ml is 2%, 12 mg/ml is 1.2%, 6 mg/ml is 0.6% and 3 mg/ml is 0.3%, so only the lowest strength is not classified.

It is the responsibility of the supplier to classify the e-liquid correctly and this is illustrative of the most likely classification.

### Nicotine labelling

When labelling nicotine-containing products, the following specific information must be included:

- **product identifiers.** Trade names or other designations, along with the EU number for nicotine (EC 200-193-3)
- **hazard and precautionary statements.** Clear information about hazards and safety precautions. This will be as follows:
  - toxic hazard pictogram.** A visual symbol indicating toxicity
  - signal word.** Either ‘Warning’ or ‘Danger’. When the concentration is classified as ‘Harmful’, the signal word is ‘Warning’; when classified as ‘Toxic’, the signal word is ‘Danger’
- **supplier information.** Full address and telephone number (landline)
- **nominal quantity.** The amount of nicotine in the package available to the general public

An example label is below. Please note that it does not include all the information that must appear on the label, just that related to GB CLP.

The label does not need to be worded exactly like this, but all the information must be included.

**Warning: contains nicotine EC 200-193-3**

Harmful\* if swallowed.

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Read label before use.

Wash hands thoroughly after handling.

IF SWALLOWED: call a POISON CENTRE or doctor / physician if you feel unwell. Rinse mouth.

Dispose of contents / container to approved disposal site, in accordance with local regulations.



[\*‘Harmful’ may need to be replaced with ‘Toxic’, depending on the concentration. See ‘Nicotine classification’ above.]

### GB CLP pictograms

Products containing nicotine concentrations classified under GB CLP, and at the levels provided for under the Tobacco and Related Products Regulations 2016 (TRPR), require the application of the ‘Health hazard’ pictogram.



The minimum size for a GB CLP hazard pictogram is 1 cm<sup>2</sup>. Each pictogram must cover at least one 15th of the label’s surface area that is dedicated to the required information under GB CLP.

If the nicotine level in the product is classified as ‘Toxic’ (that is, above 1.7% nicotine), the skull and crossbones ‘Acute toxicity’ pictogram must be used instead, in addition to the different signal word and hazard statements.



It must be noted that the classifications provided above are the usual classifications for nicotine in vaping solutions, but other additives may be classified under GB CLP and require additional labelling.

### Presentation of the information

The following rules apply to the way in which GB CLP information is presented:

- the label must be firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture
- it must be readable horizontally when the package is set down in its normal orientation
- the label, in particular the hazard pictograms, must stand out from the background
- it must be of a size and spacing that can easily be read
- a physical label is not required when the label elements are shown on the packaging itself

The hazard pictograms, signal word, hazard statements and precautionary statements must be kept together on the label.

Hazard statements must be grouped together on the label, while the order of the hazard statements can be chosen freely.

Precautionary statements must be grouped together on the label, but the order of the precautionary statements can be chosen freely.

In case more than one language being used on the label, the hazard and precautionary statements of the

same language must be grouped together on the label.

### Packaging

Packaging containing a hazardous substance or mixture supplied to the general public must not have either a shape or design likely to attract or arouse the active curiosity of children, or to mislead consumers. Furthermore, it must not have a similar presentation or a design used for foodstuff or medicinal or cosmetic products, which would mislead consumers.

Packaging must also:

- prevent the escape of the chemical
- not be adversely affected by the chemical
- be strong enough to withstand normal handling

In addition, if the packaging has a replaceable closure, this must continue to prevent escape even after repeated use.

### Child resistant closures

GB CLP usually requires that products with certain classification have child resistant closures when being supplied to consumers. Further to this, the TRPR require that electronic cigarettes or refill containers must be child resistant and tamper evident, as well as protected against breakage or leakage.

What this means, in practice, is packaging design that demonstrably meets a relevant standard for child resistant packaging.

For products containing nicotine solution, there are no specific standards at present, but it is suggested that the product protects users from access and spillage to at least the same extent as compliant packaging.

There are two relevant standards

for child resistant packaging:

- BS EN ISO 8317: Child resistant packaging. Requirements and testing procedures for reclosable packages
- BE EN ISO 13127: Packaging. Child resistant packaging. Mechanical test methods for reclosable child resistant packaging systems

It should be noted that BE EN ISO 8317 requires panel testing - that is, panels of people are required to carry out comparative testing to determine the efficacy of child resistance versus the ability of adults to open the packaging. Such testing is very expensive and time consuming to organise; BS EN ISO 13127 offers a mechanical analogue permitting this test to be conducted in a laboratory.

### Tactile warning labels

As nicotine is classified as a toxic substance, vaping products must have child resistant packaging and they must bear the tactile warning labels to alert blind and partially sighted people that they are handling a hazardous product.

Tactile warning labels must be applied to all products that are classified as toxic, very toxic, corrosive, harmful, extremely flammable and/or highly flammable, as well as to some aerosols classified as harmful, toxic and/or corrosive.

The tactile warning labels must be produced in accordance with BS EN ISO 11683: *Packaging. Tactile warnings of danger. Requirements*, which sets out detailed specifications of the label; it may appear as one of the following:

- a raised equilateral triangle in a frame 16-20 mm long and 1.5-1.9 mm thick (the corners of the triangle must be as sharp as possible and the triangle must be raised 0.25-0.5 mm above the

surface of the label)

- a smaller raised equilateral triangle in a frame 8-10 mm long and 0.8-1.2 mm thick
- a very small solid triangle with sides 3-4 mm long
- three dots, each of truncated cone shape and equally spaced. The diameter of the dot must be between 1.8 mm and 2.2 mm, and have a height of between 0.25 mm and 0.5 mm. The dots must be between 3 mm and 9 mm apart (centre to centre)

The tactile warning must not be placed on surfaces that are removed during normal use; they are not required on outer packaging, such as cardboard boxes protecting glass bottles. Other requirements are as follows:

- they must not be placed near any other embossed or raised patterns that could cause confusion
- where the packaging has a base, the tactile warning must be located on an upright handling surface near the edge, and the apex of the triangle must be positioned within 50 mm of the bottom of the pack (or as near as possible to the lid, if there is no bottom)
- if the packaging has no base (such as tubes or cartridges), then the tactile warning must be placed on the shoulder around the tube nozzle. On aerosols, the tactile warning must be positioned where the finger is placed to operate the spray
- if the warning is placed on plastic packaging with a full opening, it must be on the handling surface, as near as possible to the opening
- the tactile warning must remain tactile throughout the product's expected life

In the case of e-liquid refill bottles, this tactile warning must be on the primary container (meaning the vessel that contains the e-liquid).

### Further information

Further information for suppliers on how to comply with GB CLP can be found on the Health and Safety Executive (HSE) website. For more information on retail sale or supply, contact your local Trading Standards service.

Information about other requirements for vapes can be found in the Business in Focus guide 'Vaping products' and the In-depth Guides 'Tobacco and vapes' and 'Tobacco, vapes, etc: packaging, labelling, advertising and tracking'.

**Note:** the TRPR have a different definition of supplier to that contained in GB CLP, so please read the guidance carefully.

## LEGISLATION ETC

The laws featured in this guide / update information

### Trading Standards

For more information on the work of Trading Standards services - and the possible consequences of not abiding by the law - please see 'Trading Standards: powers, enforcement and penalties'.

### In this update

New guidance: August 2024

### Key legislation

- assimilated Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
- Tobacco and Related Products Regulations 2016

### Please note

This information is intended for guidance; only the courts can give an authoritative interpretation of the law.

The guide's 'Key legislation' links may only show the original version of the legislation, although some amending legislation is linked to separately where it is directly related to the content of a guide. Information on changes to legislation can be found by following the above links and clicking on the 'More Resources' tab.