FINAL VERSION – 9 December 2016

GUIDANCE ON E-CIGARETTES AND THE CLP REGULATION – from the Health and Safety Executive (HSE)

E-cigarettes and the CLP Regulation

Chemicals that are placed on the market must comply with the direct-acting EU CLP Regulation[1]. 'Placed on the market' means supply, making available, selling, offering for sale, providing commercial samples, or importing. The CLP Regulation applies to any chemical placed on the market including those that may be contained in a device or delivery mechanism such as e-cigarettes and refill containers (e-liquids).

The CLP Regulation requires chemicals to be *classified* (identification of all intrinsic hazardous properties), *labelled* (communicating information about the identified hazards alongside safety instructions) and *packaged* to ensure chemicals are properly and safely contained.

Classification

The CLP Regulation applies to the chemical substances and mixtures in e-cigarettes and refill containers, whether they contain nicotine or not, in the same way as for any other chemical placed on the market. Suppliers of e-cigarettes will need to classify the propellant, nicotine (where present), flavourings and any other chemical ingredient/component of the mixture, identifying the intrinsic hazardous properties of the e-liquid. Where no hazards are identified, no further compliance with CLP is necessary.

Nicotine is assigned a harmonised classification and labelling, agreed by independent experts across the European Union. Where the classification of the e-liquid is determined by an assessment of the individual component substances, this legally binding harmonised classification must be used. Alternatively, suppliers can classify the mixture directly where they have reliable, robust data on the mixture itself.

Suppliers of electronic cigarettes should ensure that they have access to competent advice on classification to allow them to make appropriate decisions about how to meet their legal duties. Classification of chemicals is a complex technical topic. It may not be possible for a non-specialist to understand the requirements sufficiently to ensure compliance. Where this is the case, relevant expertise should be sought.

Labelling

The most familiar aspect of the CLP Regulation is the red-bordered diamond shaped pictogram that illustrates the hazard/s present in a chemical, for example:

 and/or 

[1] European Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

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Once the classification is determined, the appropriate pictogram should be shown on a CLP hazard label alongside an explanation of the hazard/s (hazard statements), the appropriate signal word ('warning' or 'danger') and safety instructions (precautionary statements) to ensure the chemical is used, stored and disposed of properly.

Suppliers must label the e-cigarette product according to CLP before placing it on the market when an e-liquid mixture contained in the packaging contains one or more substances classified as hazardous based on calculation or on concentration cut-off limits.

For e-cigarettes and refill containers, the requirement for warning symbols, tactile warnings and text relating to the nicotine content depends on the nicotine strength.

The current legally binding harmonised CLP classification and labelling requirements for **nicotine** are:

International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE
			Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	
nicotine (ISO); 3-[(2S)-1-methylpyrrolidin-2-yl]pyridine	200-193-3	54-11-5	Acute Tox. 3* Acute Tox. 1 Aquatic Chronic 2	H301 H310 H411	GHS06 GHS09 Dgr	H301 H310 H411		

[Note - The asterisk in 'Acute Tox. 3*' indicates a minimum classification. A more severe hazard category may be appropriate if more information is available.]

The relevant cut-off levels that apply are 0.1% for Acute Toxicity Categories 1 -3 and 1% for Aquatic Chronic Category 2.

The revised harmonised CLP classification and labelling requirements for **nicotine** as set out in the table below becomes law in Spring 2017 (April/May 2017) and labels must be updated without undue delay in accordance with the CLP Regulation.

International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE
			Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	
nicotine (ISO); 3-[(2S)-1-methylpyrrolidin-2-yl]pyridine	200-193-3	54-11-5	Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 Aquatic Chronic 2	H330 H310 H300 H411	GHS06 GHS09 Dgr	H330 H310 H300 H411		inhalation: ATE = 0.19 mg/L (dusts or mists) dermal: ATE = 70 mg/kg oral: ATE1 = 5 mg/kg

[Note - ATEs (Acute Toxicity Estimates) are numerical values that must be used to calculate the classification for acute toxicity of a mixture which contains a substance classified for that hazard as one of its components.]

The relevant cut-off levels that apply are 0.1% for Acute Toxicity Categories 1 -3 and 1% for Aquatic Chronic Category 2.

Importantly, the hazardous nature of other ingredients should also be considered as this may also trigger a requirement for appropriate pictograms, hazard statements, signal word and safety instructions etc.

Other label elements such as the name/address/telephone number of the supplier and nominal quantity will apply as well as labelling requirements covering the design, positioning and readability of the CLP label.

The CLP Regulation and the Tobacco and Related Products Regulations 2016

Suppliers of nicotine containing e-cigarettes and their refills must comply with *both* the Tobacco and Related Products Regulations *and* the CLP Regulation.

Enforcement of the CLP Regulation and e-cigarettes

Local trading standards officers enforce the CLP Regulation, as well as the Tobacco and Related Products Regulations 2016, at retail level. The CLP Regulation is enforced at trade supply level (wholesale/manufacture) by HSE.

E-cigarettes as smoking cessation aids

E-cigarette products that are marketed as smoking cessation aids must be licensed and regulated as medicinal products by the Medicines and Healthcare products Regulatory Agency (MHRA). These are exempt from CLP and subject to medicines labelling requirements instead.

Notes:

Suppliers of electronic cigarettes and e-liquids should ensure that they have access to competent expert advice on CLP classification and labelling. Sources of advice and help include industry and trade associations at both member state and EU level and also consultancies.

- The primary source for information about the CLP Regulation, including detailed guidance, is the Helsinki-based European Chemicals Agency (ECHA) . Guidance on CLP is available at https://echa.europa.eu/guidance-documents/guidance-on-clp.

- General information about chemical classification, labelling and packaging can be found on the HSE web site at http://www.hse.gov.uk/chemical-classification/ .

Technical queries about the CLP Regulation that are not addressed in the guidance may be directed to the HSE CLP Helpdesk at ukreachca@hse.gov.uk . The HSE CLP Helpdesk provides information and responds to enquiries about the provisions of this legislation but is not able to solve business-specific problems or provide tailor-made information on how to meet CLP Regulation obligations.

HSE/MHRA
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