

Complying with CLP when making or importing candles

August 2024



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This document <u>aims to assist users in complying with their obligations under the CLP</u> <u>Regulation</u>. However, users are reminded that the text of the CLP Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. <u>Usage of the information remains the sole responsibility of the user</u>. The European Chemicals Agency does not accept any liability with regard to <u>the use that may be made of the</u> <u>information contained in this document</u>.

Version	Changes	

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1. You make or import candles - what do you need to know about your legal obligations?

A company based in the EU/EEA who makes or imports candles (including wax melts) needs to be aware that they may have legal obligations under EU chemicals regulations, and they need to consider these obligations before they place the candles on the EU market. Candle products are chemical mixtures under the EU regulations REACH and CLP.

If a candle is classified as hazardous based on the CLP criteria (due to an added fragrance, for example), then the candle must comply with both the REACH Regulation as well as all the requirements of the CLP Regulations before it is placed on the market.

2. If your candle is classified as hazardous - how do you know?

The classification of a candle will depend on the classification of the different ingredient substances that go into the product and their concentration in the final mixture. You should obtain information on the classification of each ingredient, including fragrance oils, from your suppliers (the suppliers of the ingredients if you are a candle maker or the non-EU supplier of the imported candle if you are an importer). The relevant information will be in Section 3 of the safety data sheet (SDS) provided by the supplier.

Candles are primarily made up of waxes which themselves are normally not classified in accordance with CLP. However, candles often contain additives for fragrance and colour, some of which may be hazardous. The most common hazardous property related to these additives is sensitisation, i.e., they may cause allergic reactions. Fragrance substances are often skin sensitisers, some might also be respiratory sensitisers. Candle dyes can also be classified as hazardous, but their concentration in the final candle mixture is normally very low, and therefore they are seldom relevant for the classification of the final mixture.

2.1 Classification of the candle mixture

To classify a mixture, you need to determine its health, environmental and physical hazards based on the criteria of the CLP Regulation. The ECHA website, especially the web pages on mixture classification, may be useful as a starting point:

https://echa.europa.eu/support/mixture-classification

The information to enable you to determine the classification of the final mixture should be available in the SDS provided by the suppliers of fragrances or colourants.

2.1.1 Sensitising substances

A sensitising substance may have a more or a less severe classification and the concentration limit affecting the classification of a mixture in which that substance is present will be different for the different categories. The possible hazard classes and categories and the respective concentration limits are:

- Skin sensitiser category 1A: concentration limit of 0.1%
- Skin sensitiser category 1 and 1B: concentration limit of 1%

The mixture would, in the presence of such a skin sensitising substance at a relevant concentration, be classified as Skin Sens. 1. This would require the use of the hazard statement H317 "May cause an allergic skin reaction" and the use of the relevant pictogram and precautionary statements on the label.

If the final candle mixture does not contain any sensitising ingredient substance above the relevant classification limit, it will not be classified as sensitising. However, if any of the sensitising substances is present at a concentration at or above one tenth of the classification concentration (e.g., at or above 0.1 % of a Skin Sens. 1B substance or 0.01 % of a Skin Sens. 1A substance), the substance must be mentioned on the label using the statement EUH208 'Contains (name of fragrance/substance). - May produce an allergic reaction.' Such a statement serves to warn users who are already sensitised to a particular substance.

In some cases, for particularly potent sensitisers with specific concentration limits for classification, the limit of elicitation (indication on labels and the SDS) can be even lower. Such substances are not commonly used, and it is most likely that the 0.1 and 1% limits will be applicable in the vast majority of cases related to candles.

If the composition of the perfume blend is not available, you may be able to classify your own mixture based on the classification of the perfume blend. For example, if the mixture contains 10 % of a perfume blend that is classified as sensitising, then the candle mixture is likely to contain more than 1% of a sensitiser and must be classified as Skin Sens. 1.

2.1.2 Other hazards

Other human health hazards, such as skin irritation, or in rare cases even other, more severe hazards, may be associated with certain fragrances or colourants. These – and the possibility to replace such substances with less hazardous options - will need to be considered on a case-by-case basis by suppliers who know the full composition of the candle, the fragrances and the colourants.

An environmental classification may also be required in some cases, although this is less likely.

3. Your candle mixture is hazardous – what does that mean for labelling and packaging?

If the candle mixture is classified as hazardous, or where the statement 'Contains (name of sensitising substance). May produce an allergic reaction' is required, then the candle must be labelled and packaged in accordance with CLP before it is placed on the market.

The obligation to classify a substance or mixture lies primarily on the importer or manufacturer of the substance or mixture, but the obligation to ensure that a label is CLP-compliant lies with every supplier in the supply chain.

A hazardous mixture must be packaged in packaging that complies with the CLP rules for packaging. A CLP label cannot be applied directly to a candle wax, as the candle wax is the mixture and not packaging. Further, an open glass container, aluminium foil used for tea lights, or an openwork paper box are not considered as adequate packaging for hazardous mixtures under CLP. A candle in such a container must be supplied in packaging that complies with the requirements of CLP. The label must be firmly affixed to the surface of the packaging immediately containing the candle, and positioned on the side of the packaging, so that its horizontally placed text can be easily read.

For small candles, certain labelling exemptions may apply.

4. What else should you know about CLP requirements?

4.1.1 Notification to Poison Centres

If a candle mixture is classified as hazardous to human health or hazardous due to its physical properties and is placed on the market, a poison centre notification (PCN) must be completed.

An important part of the PCN is the UFI (unique formula identifier), which is required to be placed on the label. The UFI will primarily be used by poison centres in the event of an emergency call as it helps to accurately identify the mixture. The timing for including the UFI on the label of the candle should coincide with the submission of the PCN.

You must create a UFI code for the mixture that you place on the market. If you receive a UFI from your supplier for the perfume blends or other components in your candle, you cannot reuse that UFI as the UFI of your candle. You can use them, though, as part of your PCN dossier when describing the composition and in the absence of other information.

A PCN must be completed in each Member State where the hazardous mixture is placed on the market.

Detailed information and guidance on PCN submissions and the UFI code is available at:

https://poisoncentres.echa.europa.eu/

4.1.2 Notification to the Classification and Labelling Inventory

If you are importing a candle, a perfume blend or any other mixture or a substance to make a candle, you may have the obligation to submit a notification to the Classification and Labelling Inventory. Hazardous substances, imported as such or in mixtures, need to be notified to this inventory, regardless of their tonnage.

You can find more information on these notifications, as well as advice on how to notify, at:

https://echa.europa.eu/regulations/clp/cl-inventory

Are there other legal requirements to consider?

4.1.3 Safety data sheets

Safety data sheets (SDS) are required for all hazardous mixtures placed on the market for industrial and professional users. If an SDS is required, then it must be compiled in accordance with Annex II to the REACH Regulation. Therefore, if your candle mixture is hazardous or contains hazardous substances as outlined in the REACH Regulation, you will also need to compile an SDS if you supply for professional use, for example, to restaurants.

Selling directly to consumers does not require you to produce or pass on an SDS to them; the label must give all the consumer information required.

If you are not supplying directly to the end user, for instance if you supply candles to be sold further, then you will need to provide an SDS to the distributor/retailer.

If you need to compile an SDS, or want to check the legal conformity of the ones you receive, you can refer to the Guidance on the Compilation of Safety Data Sheets, at: https://echa.europa.eu/guidance-documents/guidance-on-reach

4.1.4 Standards

There are three standards for candles which do not come under the remit of chemicals authorities. Normally, these are covered by national authorities for consumer products. The standards are:

- I.S. EN 15426 CANDLES - SPECIFICATION FOR SOOTING BEHAVIOUR

- I.S. EN 15493 CANDLES SPECIFICATION FOR FIRE SAFETY
- I.S. EN 15494 CANDLES PRODUCT SAFETY LABELS

4.1.5 Notification to the SCIP Database

Candles are considered as a 'combination of a mixture and an article'. The SCIP database, established due to certain obligations set out in in the Waste Framework Directive, contains an article category that covers 'Candles and similar articles'. Notification of articles to the SCIP database is required if an article contains a Substance of Very High Concern at a concentration above 0.1% w/w. For example, the SCIP database contains notifications of candles that contain boric acid in their wick.

Information on SCIP notifications is available at:

https://echa.europa.eu/tools

4.1.6 REACH registration

As a candle maker, you are a downstream user, and thus the REACH registration obligations are unlikely to apply to you. However, if you do import a substance as such or in a mixture from outside the EU/EEA, you might have to register the substance. The registration obligation applies to substances imported at quantities of one tonne or more per year, unless the substance is specifically exempted in the REACH Regulation.

5. Where can you get more advice?

Information on CLP in general, as well as specifically on labelling, is available on the ECHA website, under 'Guidance on CLP':

https://echa.europa.eu/guidance-documents/guidance-on-clp

If you have specific questions, you can contact the national CLP helpdesk of your country. The contact details of national CLP helpdesks are available on the ECHA website:

https://echa.europa.eu/support/helpdesks/

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