

CLP Review: classification of essential oils

Additional information on recent misleading information shared by some industry players

1. Background

Around the ongoing negotiations for the revision of the CLP Regulation,¹ various lobby organisations have recently published position papers rejecting part of the Commission's proposal, regarding impacts notably on the essential oils business, serving uses especially in fragrances and cosmetics.

These papers generally do not provide precise references to elements of the CLP regulation or the proposed revision text; yet they attract considerable attention. In the present paper, we attempt to shed light on what those organisations mean and how this relates to the present legal text and to the current situation in practice.

Overall, their statements appear to revolve around the following elements: *with the proposed new CLP, essential oils would have to be classified for hazards related to their constituents. This would put the related business at risk, although natural products are manufactured by SMEs, and have been used for centuries.*²

These statements are surprising, as

- **essential oils (or any other substances) can currently be classified based on the properties of their constituents,**
- **many essential oils are already classified for their hazards, and**
- **risks to certain businesses are not relevant to CLP as it is a communication (not regulatory) tool.**

In the following, we shall explain this statement.

2. The situation under current CLP

The current CLP text dates to 2008. Essential oils are considered substances,³ by virtue of the definition in Art. 2(7): *'substance' means a chemical element and its compounds in the natural state or obtained by any manufacturing process [...].* A substance can be made of a single constituent, or of a small or large number of constituents, i.e. individual types of molecules, which may be

¹ Regulation 1272/2008 on the classification, labelling and packaging of substances and mixtures; current consolidated version [available here](#), Commission proposal for review [available here](#).

² As examples, the IFEAT lobbying group's (essential oils and aroma trades) position paper mentions "the high stakes [...] in the change in approach to classification", asks "to allow essential oils to be treated under CLP as they are today", claims that "that the whole oil could be banned, even if the substance as a whole is not at risk", and that "essential oils are safe for use".

³ as opposed to mixtures or articles.

e.g. impurities or catalysts, or of course naturally occurring molecules harvested at the same time, as shown in the table in section 4.

The current CLP sets cut-off values for hazardous substances in mixtures in its Annex I: when a constituent identified to be hazardous and requiring classification is present in a mixture in a concentration above that cut-off value, the mixture itself is considered hazardous and must be labelled accordingly. If the constituent is present below that cut-off value, the mixture is not considered hazardous and does not require labelling.⁴ Such cut-off values exist for virtually all hazard categories and are relatively straightforward to apply.⁵

Hazardous constituents in essential oils (i.e. constituents of a mixture rather than of a mixture) are subject to the same rule: by virtue of Art. 11 (1), a hazardous constituent of a substance triggers classification of the substances, in exactly the same way a hazardous substance does for a mixture (by virtue of Art. 11 (2)).

3. Self-classification of essential oils

Next to the more well-known “harmonised classification” of substances (and therefore, mixtures) in CLP, manufacturers, importers and users of chemicals are also obliged to “self-classify” substances and mixtures (by virtue of Art. 9) when they are aware of hazards, and to notify ECHA of their assessment.⁶

The table below shows self-classifications for a few essential oils, the number of parties notifying and the hazards notified. Although some players may have shunned their responsibilities, a substantial number of market participants have taken their legal obligations seriously.

| Name | EC number | Number of notifiers ⁷ | Hazards |
|---|-----------|----------------------------------|--|
| Rose oil | 616-902-8 | 1288 | Flam. Liq. 3, skin irrit. 2, skin sens. 1, eye dam. 1, muta. 2, carc. 2, aquatic chronic 3 |
| Lavender oil <i>Lavandula angustifolia</i> | 289-995-2 | 277 | Asp. Tox. 1, skin sens. 1B, eye irrit. 2, aquatic chronic 3 |
| Thyme oil | 285-397-0 | 1286 | Flam. Liq. 3, Asp. Tox. 1, skin sens. 1, aquatic chronic |

⁴ For substances with (generally) higher potencies, specific concentration limits can be set in the process of harmonised classification, triggering classification and labelling of the mixture. at (generally) lower concentrations in the mixture.

⁵ To give a few examples: skin sensitisation (table 3.2.3 in section 3.2.3.3.6 of Annex I (original CLP)), mutagenicity (3.5.2 in section 3.5.3.1.1), STOT (3.8.3 in section 3.8.3.4.3).

⁶ ECHA's repository of notified classifications and labellings is [available here](#) and contains more than 200,000 records, as compared with hardly 4,500 substances in [the Annex VI list](#) of harmonised classifications.

⁷ Notifiers do not always agree on the set of hazards notified. The number given here corresponds to the set of hazards with the highest number of concurring notifiers.

4. Essential oils in REACH

Essential oils are also regarded by REACH as substances, and they are registered as such. The following list gives an example of the registration status of a few essential oils:

| Name | EC number | Tonnage band | Type of substance | Number of registered constituents |
|---|-----------|--------------|-------------------|-----------------------------------|
| Rose oil | 290-260-3 | 1-10 t/y | UVCB ⁸ | 7 |
| Lavender oil <i>Lavandula angustifolia</i> | 289-995-2 | 100-1000 t/y | UVCB | 21 |
| Thyme oil | 285-397-0 | 10-100 t/y | UVCB | 13 ⁹ |

This shows that although essential oils are complex substances with many constituents, those constituents are generally well-characterised – registered constituents are generally molecularly identified.

5. Impacts on animal testing?

It is often thought that additional hazard groups or changes in the CLP text would trigger or increase testing on live animals, with a strong focus on vertebrates.

Such a claim cannot be substantiated: **CLP does not contain any provisions requiring animal testing.** Testing on vertebrates and other animals is mandated by REACH for the purposes of registration (mostly annexes VII-X) and evaluation, and of course by other sectoral legislation such as that on plant protection products, biocides, or medicinal products.

6. Safety of essential oils

The hazards of essential oils notified in CLP, and linked risks, are corroborated by warnings given to pregnant women and parents, as well as by warnings on their labels.

It is not clear why the mentioned position papers link classification and labelling to economic losses, when correct labelling is common. Not warning users about known hazards and risks would certainly expose producers to impressive (economic) claims. Notwithstanding the potential existence of business impacts of classification or no classification, such information is outside the scope of CLP, which is limited to hazard identification and communication. Socio-

⁸ Substances of “unknown or variable composition, complex reaction products or biological materials”, see [ECHA's explanation page](#). In essential oils, the constituents are certainly not unknown, as shown by the substances' registered boundary compositions. Other substance categories are mono-constituent substances (one constituent > 80%) and multi-constituent substances (many constituents between 10 and 80% each), generally named as “reaction mass of [...]”.

⁹ As opposed to the two other examples, which contain an additional constituent “unknown constituents”, thyme oil appears to be exhaustively described by its 13 constituents.

economic impacts can be taken into account e.g. in a REACH restriction procedure, but not in CLP.

The intrinsic hazards of essential oils do not mean that they cannot be used safely, but that they can be used unsafely.