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**Working Document of the Working Group on Cosmetic Products**

**Application of Article 15(2) of Regulation (EC) No 1223/2009 to p-cymene**

# Background

In May 2023 the Swedish Chemicals Agency submitted to the European Chemicals Agency (ECHA) a proposal for harmonised classification and labelling of several substances, including ‘p-cymene; 1-isopropyl-4-methylbenzene’ (‘p-cymene’)([[1]](#footnote-1)). This substance is currently listed in Annex VI to the Regulation (EC) No 1272/2008 (‘CLP Regulation’) ([[2]](#footnote-2)) with the following hazard classification: ‘*Flammable Liquid Category 3, Acutely Toxic Category 3, Aspiration Toxicity Category 1, Hazardous to the aquatic environment - Chronic Hazard, Category 2*’. The Swedish authorities proposed to add ‘*Reproductive Toxicity Category 1B* *(H360FD)*’ to the existing classification.

P-cymene can be synthetically produced (manufactured) but it is also naturally present as a constituent in around 350 plant extracts at different concentrations, for example in Thyme oil: 20%, Cumin oil: 9,7%, Lemon oil: 0,5%, Neroli (bigarade) oil: 0,3%, as well as in Lavender, Bergamot, Mint, Rosemary and Eucalyptus oils. P-cymene is also present in food like carrots, oranges, grapefruits, tangerines, raspberries and many others.

Ingredients of plant origin (i.e., plant extracts) have wide use in cosmetics – they are not only used in ‘natural’ products, but practically in the majority of cosmetic products that have fragrance concentrates. Besides perfumes, according to the cosmetics industry, such plant-based compounds account for 32% of the ingredients used across the whole range of cosmetic products.

# Safety of cosmetic products

According to the Cosmetic Products Regulation (‘CPR’) ([[3]](#footnote-3)), all cosmetic products made available on the EU market must be safe for human health when used under normal or reasonably foreseeable conditions of use, while considering the presentation of a product, labelling or instructions of use and disposal, including warnings (Article 3). The CPR provides for several safety ‘levels’ which ensure that cosmetic products placed on the EU market are safe for consumers, such as the requirement that each cosmetic product has a responsible person (Article 4), that cosmetics undergo a documented safety assessment (Article 10), that a product information file is drawn up for each cosmetic product and kept for 10 years (Article 11), that prohibited substances listed in Annex II are not used, and restricted substances listed in Annex III are used in accordance with restrictions stipulated in this Annex. Moreover, the CPR allows the use of colorants, preservatives, and UV-filters only if they are listed in Annex IV, V and VI, respectively.

In case the Commission has concerns regarding the safety of certain substances, including in nanoforms, it requests the opinion of the Scientific Committee on Consumer Safety (SCCS) and where a potential risk for human health arises from a particular substance the Commission can ban or restrict the use of a substance by amending Annexes II to VI to the CPR ([[4]](#footnote-4)).

Finally, new or updated harmonised classification of substances under Annex VI to the CLP Regulation requires changing the Annexes to the CPR ([[5]](#footnote-5)):

1. Pursuant to Article 15(1) of the CPR, the use of a CMR substance of category 2, listed in Part 3 of Annex VI to the CLP Regulation, is prohibited in cosmetic products unless it has been evaluated by the SCCS and found safe for use in cosmetics.
2. Article 15(2) provides that the use of substances classified as CMR substances of category 1A or 1B, listed in Part 3 of Annex VI to the CLP Regulation is prohibited in cosmetics. By the way of exception, the restricted use of the substance could be allowed when it has been proven that all the following criteria are met: (1) the substance complies with the food safety requirements, (2) there are no suitable alternative substance, (3) the application has been made with regard to particular exposure and (4) the substance has been evaluated and found safe by the SCCS. Therefore, the pronounced safety of a substance classified as CMR 1A or 1B is not sufficient to allow its use in cosmetics.

# harmonised classification of p-cymene under CLP and its consequences for cosmetics s

On 28 November 2024 the Risk Assessment Committee (RAC) of ECHA adopted its opinion on p-cymene proposing its classification as reprotoxic category 1B. The opinion is expected to be published early 2025. The relevant Commission delegated regulation including p-cymene into Part 3 of Annex VI to the CLP Regulation will be adopted the most likely in 2026.

In accordance with Article 15(2) of the CPR, the Commission must amend the relevant Annexes to the CPR within 15 months from the adoption of the CLP delegated act.

According to the CMR Guidelines and established practice, within 6 months after the publication of the RAC opinion on p-cymene the industry can submit to the Commission the request for exemption. In case the cosmetics industry is not interested to defend the use of p-cymene in cosmetics, the Commission will proceed with the adoption of the relevant CMR Omnibus proposing the inclusion of p-cymene in Annex II to the CPR.

# Consequences of harmonised classification of p-cymene for the use in Cosmetics of substances containing more than one constituent which are extracted from plants and which are not chemically modified

The CLP Regulation, as recently revised, distinguishes between puresubstance (not containing any impurity) and complex substance (or ‘*a substance containing more than one constituent*’), of which ‘plant extracts’ (‘*substances containing more than one constituent which are extracted from plant or plant parts and which are not chemically modified as defined in Article 3, point (4), of Regulation (EC) No 1907/2006’*, further referred to as ‘plant extracts’) form a separate sub-category.

The ECHA Guidance on ‘*Impurities and (degree of) purity in CLP and in the CLH process’* ([[6]](#footnote-6)) suggests that the definition in Article 2(7) of the CLP Regulation refers to a substance as it is placed on the market by a certain company.

The Guidance then explains that the vast majority of entries in Annex VI to CLP Regulation refer to a substance (which can be a mono-constituent, a multi-constituent or a UVCB [Substances of Unknown or Variable Composition, complex reaction products or biological materials ([[7]](#footnote-7))]) without specifically mentioning impurities.

P-cymene and any plant extract containing it are two different substances which could be subject to two separate harmonised classifications.

The harmonised classification of ‘p-cymene’ cannot therefore trigger the prohibition under Article 15(2) of the CPR of the use of all natural complex substances in which p-cymene is present as a constituent.

The potentially high concentration of a CMR classified substance in a plant extract might raise concerns with regard to the safety of such substance for human health. Article 31(1) CPR enables to address such concerns as it allows the Commission to amend Annexes II to VI to the CPR ‘*where there is a potential risk to human health, arising from the use of substances in cosmetic products, which needs to be addressed on a Community-wide basis*’. The Commission has to consult the SCCS before taking the appropriate measures.

The Commission intends to launch a call for data soon after the RAC opinion on p-cymene is published, followed with the request to the SCCS for a scientific opinion on the safety of p-cymene present in plant extracts that are used in cosmetics.

Although Article 31 of the CPR does not provide for any legal deadlines, the SCCS assessment and the following Commission regulatory action would be a matter of priority as it is understood that consumers need to be reassured as to the safety of cosmetics containing the relevant plant extracts and businesses would benefit from the legal certainty.

1. () <https://echa.europa.eu/documents/10162/1a872993-3b04-4b97-b1eb-4d78aba6dd5c> [↑](#footnote-ref-1)
2. () Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; ELI: <http://data.europa.eu/eli/reg/2008/1272/oj> [↑](#footnote-ref-2)
3. () Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, ELI: <http://data.europa.eu/eli/reg/2009/1223/oj> [↑](#footnote-ref-3)
4. () For example, Commission Regulation (EU) 2024/858 added 12 substances in nanoforms to Annex II and Commission Regulation (EU) 2024/996 restricted 8 substances and prohibited one due to their endocrine disrupting properties. [↑](#footnote-ref-4)
5. () Prohibiting the substance by listing it in Annex II or restricting its use via listing it in Annexes III-VI. [↑](#footnote-ref-5)
6. () <https://echa.europa.eu/documents/10162/17218/clh_impurities_purity_en.pdf/cc0406ba-2e6c-4ee0-3082-2b2b3f123ee4?t=1534161236217>. [↑](#footnote-ref-6)
7. () Plant extracts are considered as UVCB. [↑](#footnote-ref-7)