

Member Associations  
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Downstream User Associations

15 January 2026

## Information Letter: 1224

**Subject: ECHA RAC adopts Harmonized Classification and Labelling (CLH) of Galaxolide (HHCB, CAS n° 1222-05-5, EC 214-946-9) as Reproductive Toxicant (CMR) Category 1B.**

**Related IL: none**

Dear Colleagues,

We would like to inform you that following the ECHA Risk Assessment Committee (RAC) CLH working group meeting of 28 October 2025, the ECHA RAC - 75 plenary meeting of 2 December 2025 adopted the Opinion to classify **Galaxolide<sup>1</sup> (CAS 1222-05-5) as toxic for reproduction (developmental effects) category 1B (Repr. 1B; H360D).**

The initial proposal by the French Authorities in December 2024 was for CMR 1B, Developmental effects and CMR 2 for Fertility. IFRA supported the submission of extensive comments on the CLH proposal during the public consultation held between January and March 2025 and on the draft opinion presented by the ECHA RAC Rapporteur at the ECHA RAC CLH working group meeting and ECHA RAC - 75 plenary meeting.

The IFRA CMR and ED Task Force concluded that there is no clear evidence for classification for reprotoxic/developmental effects nor any support for a classification for fertility effects in the studies being reviewed. This is supported by various previous assessments by EU authorities (RIVM 2008 and ANSES 2019) and non-EU authorities (EPA, 2014) who reviewed the exact same critical studies and found no reason to disagree with the non-classification. All studies to date confirm the conclusion for continued non-classification for both fertility and development.

The ECHA RAC agreed that a CMR 2 classification for fertility was indeed not warranted but despite our significant efforts, no support was obtained for a non-classification, or reduced classification as Repr. 2, for the developmental effects, which had already been reviewed several times before without any identified need for classification as mentioned above.

The ECHA RAC will now finalise its Opinion, publish it on the ECHA website, and ECHA will add this substance to the list of ECHA RAC 2026 Opinions to be transmitted to the European Commission for further discussion by the CARACAL in 2027.

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<sup>1</sup> 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c]pyran

Please see below the standard timelines foreseen by the European Commission for the finalisation of the current CLH process for Galaxolide. These timelines may change, and we will update the membership accordingly if this occurs.

|                                                           |                              |
|-----------------------------------------------------------|------------------------------|
| ECHA RAC Opinion adoption                                 | December 2025                |
| ECHA RAC Opinion publication                              | 2026                         |
| CARACAL discussion                                        | April – July – November 2027 |
| European Commission adoption of the ATP <sup>2</sup>      | December 2027                |
| Publication of the ATP in the Official Journal            | March / April 2028           |
| Application of the ATP (18 months after entry into force) | September / October 2029     |

We also remind you of the regulatory consequences for substances with a CLH as CMR 1B: under the EU Cosmetic Products Regulation, this results in a ban if no exemption is granted; under the EU REACH Regulation (Annex XVII), it automatically triggers a restriction at or above the classification concentration limit for Reproductive toxicity of 0.3%.

IFRA is not aware of any industry consortium being formed to apply for a derogation to continue the use of Galaxolide in cosmetic products. Therefore, in this case, Galaxolide would be banned in 2029, coinciding with the application date of the ATP. The corresponding REACH restriction will also take effect on the same date.

**Once more we re-iterate that this harmonised hazard classification is only mandatory in the European Union and that Galaxolide continues to be considered safe as used at its current use levels for consumers, according to the RIFM safety assessment.**

Galaxolide is not classified as toxic for reproduction in the IFRA-IOFI Labelling Manual and will remain unchanged based on the extensive review of the available safety data by the IFRA CMR and ED Task Force and industry's comments provided to the ECHA RAC.

**CONTACT:** If you have any further questions, please write to Cristina Arregui at IFRA ([carregui@ifrafragrance.org](mailto:carregui@ifrafragrance.org)).

Best regards,

IFRA

**Relevant links:** [Minutes of the 75th ECHA RAC Plenary Meeting](#)

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<sup>2</sup> Adaptation to Technical Progress