

Member Associations
Members of IFRA Committees
cc RIFM
Members of the JAG
Downstream User Associations

20 April 2026

Information Letter: 1235

Subject: ECHA RAC adopts Harmonized Classification and Labelling (CLH) of Tonalide (AHTN, (EC 216-133-4, 244-240-6; CAS 1506-02-1, 21145-77-7) as Reproductive Toxicant (Repr.) Category 1B.

Related IL: none

Dear Colleagues,

We would like to inform you that the ECHA Risk Assessment Committee (RAC) adopted its Opinion at the 76th Plenary meeting held in March 2026 to classify **Tonalide¹ (EC 216-133-4, 244-240-6; CAS 1506-02-1, 21145-77-7)** as **toxic for reproduction (Repr. 1B; H360Df)²**.

The IFRA CMR and ED Task Force concluded that there is no clear evidence for classification for reprotoxic effects in the studies being reviewed and IFRA supported the submission of extensive comments on the CLH proposal during the public consultation held between March and May 2025 opposing this classification.

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.

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

ECHA RAC Opinion adoption	March 2026
ECHA RAC Opinion publication	2026
CARACAL discussion	April – July – November 2027
European Commission adoption of the ATP ³	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

¹ 1-(5,6,7,8-tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one

² And additionally: STOT RE 2; H373 (thyroid), Aquatic Acute 1; H400 (M = 1), Aquatic Chronic 1; H410 (M = 1)

³ Adaptation to Technical Progress amending Annex VI of the CLP regulation

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%.

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

Tonalide 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).

Best regards,

IFRA

Relevant links:

- [Minutes of the 76th ECHA RAC Plenary Meeting](#)
- RIFM Safety Assessment:
<https://fragrancematerialsafetyresource.elsevier.com/sites/default/files/1222-05-5.pdf>