

July 2025

EUROTALC¹ statement on RAC Opinion on Talc (published on 9 July 2025)

The EU Risk Assessment Committee (RAC)'s proposal for the classification of talc as Carcinogen in category 1B is considered legally unjustified, scientifically questionable and unfair, by the Industry.

It is important to note that the proposed classification of talc is not expected to be discussed by the competent authorities (CARACAL) in 2025, but rather in 2026. The final decision by the Commission is expected at the earliest towards the end of 2026. Furthermore, any regulatory change impacting talc would not take effect before **Q3 2028** at the earliest.

RAC's proposal departs from the original proposal of the Dossier Submitter (the Netherlands) for classification of talc as carcinogen in category 2, which was already considered very conservative and scientifically questionable. RAC upgrades the proposed classification of talc to category 1B based on a very peculiar use of the CLP Regulation. In particular, and for the first time in history, RAC relies on an exceptional provision to combine limited animal and limited human data in support of the proposed conclusion.

After a careful assessment of the published RAC Opinion, EUROTALC maintains its previous position that the available data and scientific evidence on talc do <u>not</u> support the proposed classification of the substance as Carcinogen, even less in category 1B. In addition, the way in which RAC combines limited animal and human data must be subject to detailed discussions and, ultimately, reconsidered.

The alleged limited evidence is (i) selectively identified, and (ii) subject to interpretations and disagreements. It suffices to mention, for example, that IARC recently discarded as biased an important part of the human evidence, which is heavily relied upon by RAC. It is inconsistent with the whole body of available data and evidence on talc, which shows that the required level of certainty to classify the substance in Category 1B cannot be achieved.

The IARC and RAC opinions diverge both as regards the interpretation of the available scientific data, and the related conclusions. This further demonstrates that neither can support the classification of talc as carcinogen in category 1B based on strong and reliable science.

¹ EUROTALC is the talc industry's representative body for regulatory and scientific matters. It represents 95% of the European talc producers.



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The European Commission will now have to assess whether RAC's opinion is full, consistent and relevant and, if need be, address questions to RAC to remedy potential shortcomings found.² It will have to decide whether the RAC's proposal for the classification of talc as carcinogen in Category 1B is "appropriate" within the meaning of Article 37.5 of CLP, before it adopts the actual classification. EUROTALC urges the Commission to conduct this assessment thoroughly and with utmost diligence and care given, in particular, the expected major downstream consequences of the proposed classification.

EUROTALC and its members will continue to engage with all relevant authorities and stakeholders. It is vital to ensure that, on scientific and legal grounds, talc is evaluated based on robust evidence and that no unjustified regulatory burdens are placed on talc, a mineral which plays a critical role for product performance in a variety of uses.

Should you have any questions, please do not hesitate to contact EUROTALC.

Florence Lumen

Secretary General

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