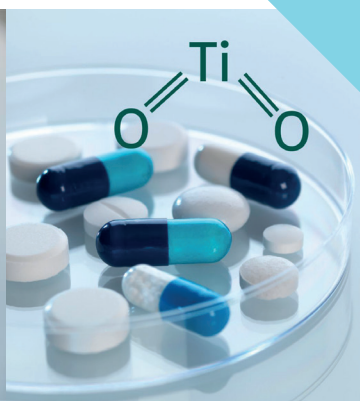
Titanium dioxide



Update – Titanium dioxide in medicinal products

Background

Three years ago, we reported about an impending ban on the use of titanium dioxide as a pharmaceutical excipient. This was initiated by Regulation (EU) 2022/63 of 14 January 2022, amending Regulation (EC) No 1333/2008, which prohibited the use of titanium dioxide as a food additive. The decision as to whether the continued use of titanium dioxide should be permitted in medicinal products was to be reviewed within 3 years on the basis of an updated EMA assessment. The European Commission has now published a staff working document dated 4 August 2025.

Strategic importance

In its report, the EMA takes the view that the technical challenges identified by the pharmaceutical industry, and reported to the EMA following a stakeholder survey, present a realistic picture of the situation. An attempt to replace titanium dioxide would pose significant logistical challenges for the industry, for both approved products and those currently under development. Even if viable alternatives to titanium dioxide were available, the transition period required for the gradual substitution of titanium dioxide in medicinal products would amount to more than 12 years, as the companies concerned would need time to reformulate their pharmaceutical portfolios and complete the regulatory process.

Furthermore, the EMA conducted an evaluation of the data relating to the safety of titanium dioxide submitted by an industrial consortium. On the basis of this data, the EMA classified any carcinogenicity risk arising from exposure to titanium dioxide in medicinal products as being negligible, for reasons including but not limited to the low quantities involved.

Because of (i) the importance of titanium dioxide in terms of the safety, quality and efficacy of medicinal products, (ii) the lack of viable alternatives at this moment in time, and (iii) the potential risk of shortages, which could be detrimental to patients considering the very large number of medicinal products concerned, the European Commission is of the opinion that titanium dioxide should continue to be used as a colouring agent in medicinal products, as provided for in Regulation (EU) 2022/63, amending Regulation (EC) No 1333/2008.

Need for action

Although there is no need for immediate action at present, the Commission draws attention to the fact that companies should actively engage with new scientific developments in the field of excipients, particularly with respect to the development of new products. In future, greater emphasis will be focused on substantiated justification for chosen excipients, including the use of titanium dioxide, in the marketing authorisation dossier. PhytoLab offers support, not only in terms of developing new products, but also with respect to coordinating and implementing pharmaceutical and regulatory revision procedures for your herbal medicinal products, right through to the submission of the necessary change notifications.

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