



Council of the European Union  
General Secretariat

**Brussels, 04 November 2019**

**WK 12346/2019 INIT**

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### WORKING PAPER

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### **WORKING DOCUMENT**

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From:	General Secretariat of the Council
To:	Delegations
N° Cion doc.:	ST 12919/19 + ADD 1
Subject:	Commission Delegated Regulation (EU) .../... of 4.10.2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation - Greek position

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Delegations will find in the Annex the Greek position on the above delegated act.

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WK 12346/2019 INIT

**LIMITE**

**EN**



Athens, 30/10/2019

Hellenic Republic



**ΑΑΔΕ**

Independent Authority  
for Public Revenue (IAPR)

Independent Authority for Public Revenue

Directorate General

General Chemical State Laboratory

Directorate of Energy, Industrial and Chemical Products

### **Greek Position on the Commission delegated act on the 14th ATP of CLP regulation**

As far as the Commission new delegated act on the 14th ATP of CLP regulation is concerned, we would like to inform you that, the Greek Competent Authority supports the classifications included in the above mentioned delegated act, except the classification of Titanium Dioxide (TiO<sub>2</sub>).

We cannot support the classification of Titanium Dioxide (TiO<sub>2</sub>), position already expressed in the REACH COMMITTEE and CARACAL meetings of the last months, for the following reasons:

1. The classification of Titanium Dioxide represents a borderline case between Carcinogenicity, Category 2 and no classification because:
  - An overload method (rats are exposed to exceptionally high concentrations) has been used to classify the substance as Carcinogen cat. 2 (the high concentrations at which findings of lung tumours were described in the study by Lee *et al.* (250 mg/m<sup>3</sup>) which “clearly exceeded the maximum tolerable dose (MTD)” (RAC opinion).
  - The mode of action presents distinct differences between rats and humans in their response to the overload method. It is clear that inhaled particles are retained to a greater degree in the human lung interstitium compared to rats, where the particles remain in the alveolar space. In rats, the particles are removed from the alveolar through the activation of macrophages and extensive inflammation is observed. In humans, mainly systemic inflammation has been observed, the origin of which, according to the RAC, could not totally rule out local inflammatory response. Therefore, the above mentioned mode of action *cannot be considered “intrinsic toxicity” in a classical sense* but is characterized as particle toxicity. This was also recognized in RAC opinion.
  - TiO<sub>2</sub> belongs to the class of poorly soluble low toxicity particles (PSLT). These substances consist a category on their own and the applicability of TiO<sub>2</sub> classification refers only to its PSLT character.
2. There is a need of further scientific discussion on classification of the case of poorly soluble low toxicity particles (PSLT) separately for better regulatory management in the framework of CLP Regulation.
3. COM, based on the RAC's opinion on TiO<sub>2</sub>'s “borderline intrinsic risk”, proposes the classification of TiO<sub>2</sub> mixtures (liquids and solid) by introducing new provisions to this ATP (3 new notes, 2 new EUH statements), which are not included in RAC opinion. This approach needs more scientific discussion.
4. Finally, we believe that the inclusion of this classification in Annex VI would lead to an overestimation of the hazard and consequently will have a large impact in the broad TiO<sub>2</sub> industry and circular economy.