

**From:** [REDACTED]  
**Sent:** 30 November 2018 16:45  
**To:** SG UNITE E2  
**Subject:** FW: Titanium dioxide alliance / ongoing Inter-Service Consultation / 14th ATP list to the Annex VI of regulation (EC) No 1272/2008  
**Attachments:** TiO2 Alliance - Inter-Service Consultation on the 14th ATP to the CLP regulation 1272-2008.pdf

[REDACTED]

[REDACTED]

**From:** [REDACTED]  
**Sent:** Friday, November 30, 2018 11:21 AM  
**To:** [REDACTED]  
**Subject:** Titanium dioxide alliance / ongoing Inter-Service Consultation / 14th ATP list to the Annex VI of regulation (EC) No 1272/2008

[REDACTED]

Please see attached our letter regarding titanium dioxide (**TiO<sub>2</sub>**) and the **started Inter-Service Consultation** on the 14th adaptation to technical progress (ATP) to the Annex VI of regulation (EC) No 1272/2008. We took the liberty to send this letter to several Commissioners.

We are convinced that the substance titanium dioxide is safe for consumers and has a societal function. The proposed classification broadens the scope of the regulation considerably and has unintended consequences such as no recyclability for millions of products. Alternatives for a way forward have not been fully explored. Please note that a considerable number of Member States remain with an objection to a classification according Annex VI. They point to non-existing exposure for consumers and extensive negative consequences for mixtures and articles that use TiO<sub>2</sub> (e.g. a ban of most colours from school-paint boxes).

We thank you for taking time to consider our letter and remain at your disposal for any further discussion with you on this measure.

Kind regards,



[REDACTED]

CEPE - European Council of the Paint, Printing Ink and Artists' Colours Industry  
Av. E. van Nieuwenhuysse 6 | B-1160 Brussels | Belgium



Website : [www.cepe.org](http://www.cepe.org)



As of 1 January 2019 find us at 172 Blvd du Triomphe - 1160 Brussels



30. November 2018

***Inter-Service Consultation  
on the 14<sup>th</sup> ATP list to the Annex VI of Regulation (EC) No 1272/2008***

The European Commission services have started an Inter-Service Consultation with the aim to update Annex VI (Harmonised classification and labelling for certain hazardous substances) of Regulation (EC) No 1272/2008 for a total of 20 substances. We write to you concerning the substance **titanium dioxide (TiO<sub>2</sub>)** which is included in this list. The industries represented by the signatory associations are users of TiO<sub>2</sub>. We believe that the hazard that has been observed with this substance should not follow the way of an Annex VI entry and we have for that the following reasons:

TiO<sub>2</sub> is safe for consumers and has a societal function

TiO<sub>2</sub> is a chemically inert white powder that is widely used as pigment in products like paints, inks, plastics but also in many other industries such as paper, construction, glass, steel, pharmaceutical, cosmetics, leather, and textiles. It is used in any product that needs whitening. TiO<sub>2</sub> provides the highest opacity by far and has no equivalent technical replacement. The substance is an ingredient that is incorporated during manufacturing into these end-products. Consumers buy these end-products and have no access to the powder form of TiO<sub>2</sub>.

The proposed classification broadens the scope of the regulation considerably

It is proposed to classify TiO<sub>2</sub> as Carcinogenic Cat. 2 'suspected of causing cancer by inhalation'. The observed toxicological effect result is not specific to the substance but to the overload mechanism that can be observed with any inert dust. A classification of TiO<sub>2</sub> will put dust effects into the scope of the regulation and thereby sets a precedent for roughly 300 substances with similar dust effects.

There are existing safeguards for workers against dust

Relevant dust levels of TiO<sub>2</sub> will only occur at the workplace where rules on occupational safety have to be followed. With no hazard for the consumer we consider a classification inappropriate. Warning the European citizen for inhalation of TiO<sub>2</sub> dust is ineffective or even misleading, because it is incorporated in the mixtures and lung overload is irrelevant. Exempting mixtures from classification would prevent at least this nuisance.

Unintended consequences by a classification: no recyclability for millions of products

Following the proposed classification, products at end of life or left-over that contain 1% or more of titanium dioxide would have to be considered as hazardous waste and could not be used for recycling. Other legislation would ban products that contain TiO<sub>2</sub>. Under the toy safety directive most colours would be banned from school-paint boxes. To mitigate these impacts the European Commission services consider exemptions.



Alternatives for a way forward have not been fully explored

After expert meetings (CARACAL & REACH Committee) **a considerable number of Member States remain with an objection to a classification according Annex VI.** They point to non-existing exposure for consumers and extensive negative consequences for mixtures and articles that use TiO<sub>2</sub>.

The Member States that object to a harmonised classification are in favour of a discussion on exposure levels for workers and consider occupational dust limits as the more appropriate instrument. Such alternative proposal has been tabled by Germany. It has no effect on downstream legislation and establishes safeguards where needed.

By using an Annex VI entry for TiO<sub>2</sub>, the scope of the regulation would be broadened to roughly 300 substances which may be expected to show similar overload dust effects. If such inert dusts were subject to the rules for Occupational Health it would be a lot more effective and proportionate. Even with 'mixture exemptions' the downstream legislation has to be adapted with every next such substance.

Our request

We call on you to take note of the reasons mentioned here in evaluating the Annex VI entry of TiO<sub>2</sub> during this Inter-Service Consultation.

We remain at your disposal for any further discussion with you.

Yours sincerely,

Jan van der Meulen  
Managing Director, European Council of  
the Paint, Printing Ink and Artists' Colours  
Industry (CEPE)

Alexandre Dangis  
Managing Director, European Plastics  
Converters (EuPC)

Dr. Roger Doome  
Secretary General, Industrial Minerals  
Association – Europe (IMA-Europe)

Philip Bruce  
Managing Director, Association of the  
European Adhesive & Sealant Industry  
(FEICA)

John Dixon  
Director Regulatory Affairs,  
Flexible Packaging Europe (FPE)

Dr. Martin Kanert  
Executive Manager, European Printing Ink  
Association (EuPIA)

Antonio Caballero González  
General Secretary, European Mortar  
Industry Organization (EMO)

Mauro Scalia  
Director Sustainable Businesses,  
European Apparel and Textile  
Confederation (EURATEX)

Dr. Alberto Arnavas  
Director General, European Federation for  
Construction Chemicals (EFCC)

Patrizia di Mauro  
Secretary General, International  
Association of Painting Contractors  
(UNIEP)



Gustavo Gonzalez-Quijano  
Secretary General, The European Leather  
Association (COTANCE)

Beatrice Klose  
Secretary General, European Federation  
for Print & Digital Communication  
(INTERGRAF)

Bjoern-Markus Sude  
Director, I&P Europe Imaging & Printing  
Association (I&P Europe)

Susan Hancock  
Secretary General, European Lubricant  
Association (ATIEL)

Dr. Wilhelm Rauch  
Managing Director, Industrievereinigung  
Chemiefaser e.V. (IVC)





Joint Transparency Register  
Secretariat



Brussels,

[REDACTED]  
Researcher and campaigner

[REDACTED]  
Sent only by e-mail to:  
[REDACTED]

Ref: TR-A-2018-72

**Subject: Closure of the alert procedure regarding the non-registered activities of the entity Titanium Dioxide Manufacturers Association (TDMA), a sector group of CEFIC (European Chemical Industry Council)**

[REDACTED]

The Joint Transparency Register Secretariat (JTRS) refers to your alert TR-A-2018-72, which you submitted on behalf of Corporate Europe Observatory (CEO) on 10 July 2018 concerning the entities Titanium Dioxide Manufacturers Association (TDMA) and Venator.

As you were informed on 1 August 2018, in order to follow up to your alert, the Joint Transparency Register Secretariat has been in contact with CEFIC (TR ID: 64879142323-90), of which TDMA is a sector group, in order to receive additional clarifications with regard to the activities and status of this organisation.

It has emerged that as a sector group of CEFIC, TDMA does not have its own legal personality<sup>1</sup>. All legal references on the TDMA website point to the legal personality of CEFIC, which is officially registered in Brussels, as stipulated in the Moniteur Belge, with the registration number 0412849915.<sup>2</sup> In fact, TDMA is one of up to 70 sector groups of CEFIC, none of which are currently registered in the Transparency Register directly.

<sup>1</sup> <https://specialty-chemicals.eu/tdma/>

<sup>2</sup> <http://www.ejustice.just.fgov.be/tsv/tsvf.htm>

Therefore, while the JTRS cannot require that TDMA itself register in the Transparency Register, it has taken note of your concerns for more transparency regarding the activities of the sector groups of CEFIC. This is why, in its contacts with CEFIC, the JTRS has sought to identify possible areas of improvement in its declaration.

As a follow up to the alert, CEFIC has already taken the following measures to increase the transparency of its activities:

- CEFIC now includes the activities of CEFIC's sector groups in its registration in the Transparency Register;
- CEFIC's registration now provides a hyperlink to a full list of its sector groups (ca. 70) in its registration;
- CEFIC has given instructions to the staff of its sector groups to clearly identify themselves as such, when acting as representatives of CEFIC sector groups with the objective of directly or indirectly influencing the formulation or implementation of policy and the decision-making processes of the EU institutions.

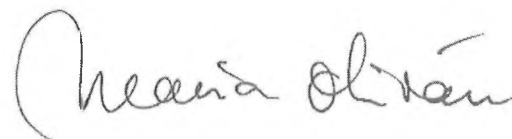
In the context of this alert, the consultancy Fleishman-Hillard has also corrected its registration and no longer provides separate account statements for CEFIC and its sector groups.

Furthermore, the JTRS finds that while it may be neither warranted nor practical for CEFIC to oblige approximately 600 members to individually register in the Transparency Register, the JTRS has encouraged CEFIC to invite its members to register those activities that the latter perform in their own name and outside of CEFIC's activities.

In this spirit the JTRS has also invited the entity Venator, which is a member of CEFIC, to register those activities in the Transparency Register falling outside the activities of the umbrella organisation and which are in the scope of the Interinstitutional Agreement on the Transparency Register.<sup>3</sup>

The JTRS finds the above implemented measures to be a sufficient and adequate response with regard to the case at hand, and fully in line with the guidelines for registrants. It has therefore decided to close the alert procedure.

Yours sincerely,



María Oliván-Avilés  
Coordinator of the Joint Transparency Register  
Secretariat

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<sup>3</sup> [https://eur-lex.europa.eu/legal-content/en/TXT/?uri=uriserv:OJ.L\\_.2014.277.01.0011.01.FNC](https://eur-lex.europa.eu/legal-content/en/TXT/?uri=uriserv:OJ.L_.2014.277.01.0011.01.FNC)





## EUROPEAN COMMISSION

Secretariat-General

Directorate D - Policy Co-ordination I  
SG.D.3-Resource Efficiency

Brussels, 19 July 2018

### NOTE TO THE FILE

**Subject: Meeting with CEPE on 18 July 2018 on the CLP classification of titanium dioxide**

**Participants:**

[REDACTED] (CEPE); [REDACTED] (CEPE); [REDACTED] (EUPC); [REDACTED] (EFCC) and [REDACTED] (SG.D3)

The meeting was organised after several requests from CEPE with a view to inform about the potential CLP classification of titanium dioxide as a carcinogen.

**Summary:**

The CEPE participants explained the history of the file that had started off under unfortunate circumstances under REACH where France was in charge of a substance evaluation of titanium dioxide. In their work they wanted to focus on the smallest particles (nanomaterials), but this was rejected by the industry, leading to two cases at ECHA's Board of Appeal. The ensuing consequence was that France then applied the results from two rat studies to conclude on the hazardousness of all forms of titanium dioxide. Even if the rat tests did not mimic any real-life exposures they were unanimously supported in the further process in RAC leading to the conclusion that titanium dioxide is a category II carcinogen.

If the Commission follows the normal logic of the CLP Regulation, this will have server consequences due to related regulatory triggers. All paints will be labelled and thereby diminish the purpose of labelling, but also lead to product bans (toys, cosmetics) and other disproportionate / unintended effects (building waste being hazardous, effects on eco-labelled products, public procurement of building materials).

CEPE supported a new proposal tabled last week by the UK and SI whereby titanium dioxide instead of being listed in Annex VI to CLP instead would have a new entrance in Annex II that will demand a softer kind of labelling on dusty mixtures. This could then be extended to other powders, which like titanium dioxide were not intrinsically hazardous, but formed a risk when inhaled, solely due to their small particle sizes.

Asked about CEPE's views on the most recent informal proposal from ENV and GROW whereby most paint products would be excluded, they maintained that it was better than

the starting point, but that it would still leave open the question on waste and also many building materials (cement, mortar etc.).

SG welcomed the information and invited CEPE to continue their dialogue with ENV and GROW, who are lead services for the file.



**From:** SG UNITE D3  
**Sent:** 19 June 2018 14:08  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: Industry Statement on the Harmonized Classification of Titanium Dioxide (TiO<sub>2</sub>)

Dear [REDACTED],

Thank you for forwarding the letter on behalf of 15 European associations, the European Council of the Paint, Printing Ink and Artists' Colours Industry expressing concerns linked with the on-going process under the CLP Regulation on the possible classification of TiO<sub>2</sub>. We have read the letter with interest and we see that the organisations are already very familiar with content of the on-going technical discussions between the Commission services and Member State experts as well as the procedural steps still to be taken. Given the highly technical nature of your concerns and the fact that the file is handled by our colleagues in DG Environment and in DG GROW, we suggest that you meet with them, if you believe that is still relevant after last week's meeting of the competent authorities to REACH, where we have understood the possible classification of TiO<sub>2</sub> was discussed in the presence of also industrial stakeholders including from Cefic.

Kind regards,

On behalf of [REDACTED],

[REDACTED]  
European Commission  
Secretariat-General  
Directorate D - Policy Co-ordination I  
SG.D.3-Resource Efficiency

**Expéditeur:** [REDACTED] >  
**Date:** 31 mai 2018 à 18:24:05 UTC+2  
**Destinataire:** [REDACTED] >  
**Objet:** Industry Statement on the Harmonized Classification of Titanium Dioxide (TiO<sub>2</sub>)

Dear Mr [REDACTED]

on behalf of 15 European associations, the European Council of the Paint, Printing Ink and Artists' Colours Industry is pleased to submit a letter to you regarding the potential classification of Titanium Dioxide (TiO<sub>2</sub>). Please find the industry statement enclosed to this email. We have sent similar letters to the European Commissioners Timmermans, Bieńkowska, and Vella.

We thank you for taking time to consider this important matter. We would welcome the opportunity to discuss our proposals at your convenience.

We would welcome an acknowledgment of receipt. Thank you in advance.

Kind regards,



Addressed to:

M. [REDACTED] Head of Unit D3 - Resource Efficiency, Secretariat General of the European Commission

Brussels, 31 May 2018

**Industry Statement on the Harmonized Classification of Titanium Dioxide (TiO<sub>2</sub>)**

Dear [REDACTED]

We would like to inform you of the intention by the Directorates-General GROW and Environment to classify Titanium Dioxide as 'suspected of causing cancer through the inhalation route'. This will set a precedent with many significant impacts. As major downstream users of TiO<sub>2</sub>, a potential labelling of most of our products or raw materials will entail strong consumer uncertainty and reservation, followed by commercial losses with impacts on growth and job security for our millions of employees, mostly at SME's.

Following the RAC opinion of 14 September 2017, the relevant units consider tabling a proposal to update the Annex VI of Regulation (EC) No 1272/2008 as early as June 2018. According to the lead units, the legislative planning foresees a discussion at REACH Committee on the 13 June and a vote in September 2018.

Before tabling the proposal, we would welcome the consideration of our concerns and the acknowledgement of our proposals to first have an impact assessment on the classification or a risk management option analysis and the finalisation of the REACH substance evaluation on Titanium Dioxide. Please take into account the full-day CARACAL meeting on 23 April 2018, where several Member States including Germany questioned the classification of Titanium Dioxide and the continuation of the process as a whole.

According to the interinstitutional agreement of 13 April 2016 on Better Law-Making, the European Commission will carry out an impact assessment for secondary legislation which is expected to have significant economic, environmental or social impacts. A classification of Titanium Dioxide will have significant impacts on all three dimensions, which have not yet been considered at all. It is furthermore important to note that a classification will stand against the objective of (EC) No 1272/2008 and other EU initiatives like the EU Circular Economy. Therefore, we call for an impact assessment on the expected classification proposal or a risk management option analysis.

The proposed classification is merely based on a non-substance specific dust effect. If a dust effect were to be included into (EC) No 1272/2008, the scope of what is classified and labelled will be massively extended with an automatic domino effect on other legislations. Such precedent lays the foundation for a classification of potentially hundreds of other poorly soluble substances. A labelling of all Titanium Dioxide-containing products alone will lead to label fatigue, to the detriment of consumer protection and against the intention of the regulation to properly inform on hazard. Regulation (EC) No 1272/2008 could fail.

Following a classification, many materials containing more than one percent of Titanium



Dioxide would be considered as hazardous waste. This would become reality for a large variety of materials, including paints, inks, plastics, coated articles and construction products. In contrast to the EU Circular Economy, the aim of a high recyclability rate could not be achieved any more for those products. Since  $TiO_2$  has the highest opacity among white pigments, the environmental footprint of paints containing  $TiO_2$  substitutes will be much higher, as they require at least 3-4 extra layers of paint.

In addition, we would like to point to the importance of having a feedback period of 4 weeks on the draft measure. Currently, the relevant units are considering different derogations to fix the consequences of a classification. Until now, no enforceable entry or exemption has been proposed which would avoid inappropriate classification of mixtures. To our knowledge, the classification of dusts has never been discussed in Europe. With this dossier it is the right time to have a proper consideration before creating a precedent.

For all of these reasons, we call on you to apply the better regulation principles and to pursue a fundamental policy discussion that has started with the Member States – in particular to assess whether Regulation (EC) No 1272/2008 is the right regulatory instrument to address the concerns at stake, if any – before moving ahead with a classification of this individual substance on the grounds of a generic effect.

Finally, we would like to point to the ongoing REACH substance evaluation of Titanium Dioxide by France. We propose to first finish this parallel process, before considering any classification in order to ensure regulatory quality and alignment.

We thank you for taking time to consider this important matter. We would welcome the opportunity to discuss our proposals at your convenience.

Yours sincerely,

Jan van der Meulen  
Managing Director, CEPE

Gustavo Gonzalez-Quijano  
Secretary General, COTANCE

Dr. Alberto Arnavas  
Director General, EFCC

Antonio Caballero González  
General Secretary, EMO

Dr. Martin Kanert  
Executive Manager, EuPIA

Manfred Meller  
General Secretary, EWIMA

Bjoern-Markus Sude  
Director, I&P Europe

Patrizia di Mauro  
Secretary General, UNIEP

Alexandre Dangis  
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Dr. Roger Doome  
Secretary General, IMA-Europe

Mauro Scalia  
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EURATEX

Philip Bruce  
Managing Director, FEICA

Beatrice Klose  
Secretary General, INTERGRAF

Olaf Kral  
Chair HSE Committee, ATIEL