

TiO₂ IN PVC-U WINDOWS AND DOORS

Factsheet on the use of TiO₂ in PVC-U profile systems

Recent legislative action on EU-level has provoked questions on TiO₂ inside and outside of the PVC profile industry. This factsheet will provide an overview of a) the legal & policy and b) the scientific dimension to the TiO₂ discussion.

I. The Legal and Policy Dimension

1. Classification of Titanium Dioxide as Carcinogen (category 2) by inhalation

In May 2016, ANSES submitted a proposal to ECHA for the classification of TiO₂ as a presumed carcinogen (category 1B) by inhalation.

After evaluating the proposal, ECHA's Committee for Risk Assessment (RAC) decided in September 2017 that there was insufficient evidence to classify TiO₂ in category 1B. Instead, the RAC was of the opinion that the evidence could only support a lower classification of TiO₂ as a suspected carcinogen (category 2) by inhalation only.

The regulatory discussions have consequently concluded that there are no risks for consumers, as the extremely high levels of exposure that would be required for TiO₂ to be hazardous are unrealistic under normal and foreseeable consumer conditions. The hazard described by the RAC is therefore not expected to occur in any real-world scenario and is mainly a theoretical risk in the workplace.

According to the RAC, the hazard profile described for TiO₂ extends to all poorly soluble low toxicity substances (PSLTs), a group of 300+ substances. This highlights that the suspected hazard for TiO₂ is a general issue associated with the potential inhalation of dust/powdered substances in the workplace. The classification of TiO₂ would therefore start a domino-effect for this group of substances, as all would logically have to be treated equally.

However, taking a substance-by-substance regulatory approach would result in years of regulatory action, requiring substantial time and effort, which is why some stakeholders have also proposed to address all of these PSLTs in a grouped way targeted at the workplace as a better solution.

In October 2019 the European Commission moved forward with its proposal to classify TiO₂ as carcinogen (category 2) by inhalation, although multiple Member States were against such a classification. They had the opportunity to raise objections in the Council likewise as the European Parliament. None of the two made use of this right (due to insufficient internal majorities) leading to the final adoption of the decision.

The classification had to be implemented 18 months after entry into force of the legal instrument (9th of March 2020).

As of 1st of October 2021 TiO₂ is classified as carcinogen (category 2) by inhalation only. In line with the applicable derogation, this classification only applies to mixtures in powder form containing 1% or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter ≤ 10 µm.

2. Classification of Waste containing TiO₂

The classification following REACH and CLP Regulation produces legal consequences following European waste legislation.

Classification and labelling as carcinogenic cat. 2 would trigger an automatism under Decision 2000/532/EC (list of waste) requiring classification as hazardous of wastes containing TiO₂ in concentrations of 1% or more (i.e. of pre-consumer and post-consumer PVC window waste).

Since it was decided that only TiO₂ in powder form constitutes a risk that justifies classification, the European Commission proposed to amend its “Guidance Document on the Classification of Waste”. The amended notice should clarify that waste containing substances that have a harmonized classification under CLP has to be classified as hazardous only if it is in the same form as that in which the substance is classified.

However, the amendment has not yet been agreed on and even if it enters into force it is not binding for Member States. They can rely on Decision 2000/532/EC for requesting hazardous waste classification of TiO₂ containing waste.

II. Scientific Dimension

3. Titanium Dioxide in the Workplace

The regulatory discussions between the Member States, the European Commission and interested parties have concluded that the potential hazard described in the RAC’s assessment of TiO₂, is limited to the workplace.

This is because the suspected hazard described for TiO₂ only applies to inhalation. It is based on ‘particle toxicity’ – a secondary dust effect, and is not intrinsic to TiO₂ specifically – which is caused by prolonged inhalation of respirable particles at an extremely high concentration. If these extreme conditions are removed, the particle-form of TiO₂ is non-hazardous.

Protection against dust and powder exposure is mainly a matter for health and safety in the workplace. Dust management measures can include the use of personal protection equipment. As TiO₂ tends to be fully incorporated into the end product, potential consumer exposure to TiO₂ in powder form is extremely low.

Most EU Member States already have general limits for dust in the workplace in their occupational health and safety legislation, to prevent impairment of respiratory function due to a general dust effect.

These worker protection laws and threshold are not related to or impacted by the recent classification of TiO₂ based on the CLP.

4. Titanium Dioxide in end-user Products (i.e. Windows)

The powder form of titanium dioxide presents no risk to consumers when incorporated in a finished product.

In September 2016, the European Food Safety Authority's (EFSA) Scientific Panel on Food Additives and Nutrient Sources published an Opinion confirming TiO₂ is considered safe for use even in food. It is also approved for use in a variety of products and materials, including sunscreen, toothpaste and pharmaceuticals.

In PVC windows, TiO₂ prevents degradation of the material from daylight, particularly UV light. The substance is firmly embedded in the PVC matrix, erasing any risk of inhaling TiO₂ for the consumer.

Practical consequences for the PVC profile industry

The points explained above result in different obligations for all parts of the PVC window value chain. These have already entered into force or may do so depending on the outcome of on-going legislative processes.

Value-chain Position	Obligation	Comment	Entry into Force
TiO ₂ Supplier	The label on the packaging of solid mixtures containing 1 % or more of titanium dioxide shall bear the following statement: <i>EUH212: 'Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.'</i>		1.10.2021
Compounder (resin or recylate)	Follow safety data sheet received by supplier		1.10.2021
	The label on the packaging of solid mixtures containing 1 % or more of titanium dioxide shall bear the following statement: <i>EUH212: 'Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.'</i>	Although the mixture would not be classified, there is for the time being a labelling obligation. It is expected an amendment to the CLP should be adopted during the transition period confirming the	

		conditions for exemption of labelling of those mixture that are not classified.	
Converter	Follow safety data sheet received by supplier		1.10.2021
Window Manufacturer	None related to CLP. National worker protection laws and thresholds apply.	CLP does not apply to articles (only substances and mixtures)	In force
Waste Operator/Recycler	National waste legislation applies	Based on current Decision 2000/532/EC, Member States are obliged to request hazardous classification of window waste containing ≥ 1 % TiO ₂	1.10.2021

Table 1: Operational requirements based on the TiO₂ classification

5. Literature

ECHA, The European Chemicals Agency. Titanium Dioxide Substance information, <https://echa.europa.eu/substance-information/-/substanceinfo/100.033.327>, accessed December 2019

TDMA, The Titanium Dioxide Manufacturers Association. www.tdma.ino, accessed December 2019

Brussels, 4th March 2020