



# Ti-Pure™

## Titanium Dioxide

## EU Declaration of Compliance for Food Contact Materials for Plastics

The Chemours Company, 1007 Market Street, Wilmington, DE 19801 USA, which manufactures and then imports the following products into the EU via Chemours Belgium BVBA, hereby declares that the composition of our products identified as:

### Ti-Pure™ Titanium Dioxide Pigments for Plastics Grade: R-104, R-105 and R-960

have the following regulatory status relative to the use as additives in plastics food contact materials:

#### European Union

The above listed product, as supplied complies with:

- Commission Regulation (EC) n° 1935/2004, as amended by Regulation (EU) 2019/1381.
- Commission Regulation 10/2011/EU on plastic materials and articles intended to come into contact with food, as amended.

Colorants in accordance with Article 5.2(b) and Article 6(2) are not required to be listed in the Union list of authorised substances (Annex I) when covered in national law. However, the substances present in the above listed Ti-Pure™ titanium dioxide pigment appear in Annex I and hence the product complies with the Regulation, under the condition that the finished article meets the following migration limits.s:

**Overall Migration Limit (OML):** 10 mg/dm<sup>2</sup> (Article 12)

**Specific Migration Limits (SML):** N/A

### General restriction outlined in Annex II (as last updated by EU 2020/1245)

Except for aluminum, none of the elements listed in Annex II are intentionally added, but trace amounts of certain elements may be present.

With the exception of ionic aluminum, the presence of Annex II substances are below the listed SML's in accordance with migration testing performed directly on pigment under severe testing conditions for metals migration (3% acetic acid food simulant, 4 hours at 100 °C followed by 10 days at 60 °C, no polymer matrix)<sup>1</sup>.

Ionic aluminum migration under the prescribed severe testing conditions, exceeded the migration limit of 1 mg/kg food of ionic aluminum. As these are tests performed directly on pigment, they are highly precautionary. When incorporated in polymer in the form of an article the migration is substantially lower<sup>1</sup>.

The migration of aluminum ions from non-polar polymers is typically less than 0.1 mg/kg food. However, uses in polar polymers, where swelling occurs in contact with food stuffs simulated by 3% acetic acid, should be limited to conditions that do not exceed the AI SML of 1 mg/kg food.

Hence we advice that plastic materials and articles produced with these grades in polar polymers should be verified for compliance with the ionic aluminum migration limit of 1 mg/ kg food.

There are no known sources of Primary Aromatic Amines (PAA) in the production process of titanium dioxide, and hence PAA are not expected to be present.

The products are produced according to our quality management system, which complies with the

requirements of the Regulation (EC) n° 2023/2006, on good manufacturing practice for materials and articles intended to come into contact with food.

Presuming appropriate processing following the Good Manufacturing Practices Regulation (EC) n° 2023/2006, the above listed Ti-Pure™ titanium dioxide pigments can be used in the countries of the European Union for the manufacturing of plastic materials and articles according to article 3 of Regulation (EC) n° 1935/2004.

*It remains the responsibility of the end-user to ensure compliance of the finished articles with the above-mentioned Migration Limits*

### Dual Use Additives

TiO<sub>2</sub> is allowed to be used as a food additive under entry E171 in annex II of Regulation EC n° 1333/2008 and hence is considered as a “Dual Use” additive. Ti-Pure™ titanium dioxide pigment grades, however, do not meet the criteria for E171 use in food.

However, according to the Union Guidelines on Regulation (EU) 10/2011, Ti-Pure™ products should be considered as dual use additives and manufacturer’s responsibility under Article 3 of Regulation EC n° 1935/2004.

### Specification of Use

There are no Specifications of Use for any of the substances in Ti-Pure™ titanium dioxide pigments.

### Status in countries with additional national legislation on colorants:

In addition to being compliant with the requirements in Reg. EC n° 10/2011, the above listed Ti-Pure™ pigments also comply with the following national legislations for additives used in plastic materials and articles foreseen to come into contact with food:

- **Germany:** “BfR Empfehlung” (BfR recommendations) IX / purity of colorants for plastics and other polymers used in commodities; (purity criteria), dated June 1<sup>st</sup> 2019.
- **Italy:** “Decreto Ministeriale” (= Ministerial Decree) of 21 March 1973, Art. 12 / purity of colorants for plastics, as amended.
- **Netherlands:** “Commodities Act (Packaging and Utensils Decree)” of Jan 1<sup>st</sup> 2017, Chapter I Plastics & XI Colorants and pigments. (Purity criteria on pigment/colorants), as amended,
- **Spain:** “Real Decreto” 847/2011, de 17 de junio, Annex II / Mandatory identification and purity conditions applicable to colorants for use in polymers coming into contact with food, as amended.

- **Switzerland:** DFI Swiss Ordinance 817.023.21 of 16 December 2016, and updated by RO 2019 3371 on Dec. 1<sup>st</sup> 2019, as amended, on materials and articles foreseen to come into contact with food stuff; including:

The general provisions outlined in Chapter 1, 2 and 3; and

The provisions applicable to plastics outlined in Chapter 5, and substance Specific Migration Limits (SML) listed in Table 1 of Annex 2; on condition that the products comply with the Regulation, under the condition that the finished article meets the following migration limits:

**OML:** 10 mg/dm<sup>2</sup> or 60 mg/kg (food) (Article 12)

**SML:** not applicable

The above listed Ti-Pure™ meet the general requirements applicable to pigments and colorants in Annex 2 Section 2.2 Table 3.8

General restriction outlined in Annex 2 Section 2.3.1:

Please note that above mentioned Ti-Pure™ grade contains aluminum in oxide matrices that can be dissolved in acidic media releasing ionic aluminum (Al) that has an SML of 1mg/kg food. Based on testing, and in accordance with EFSA guidance, we advise that plastic materials and articles produced from above mentioned grades should be verified for compliance to the aluminum SML.

It remains the responsibility of the end-user to ensure compliance of the finished articles with the above-mentioned Migration Limits

As a consequence, compliance is granted in the following countries which do not have national laws on the use of colorants (in plastics) for materials and articles intended to come into contact with food: **Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden and United Kingdom.**

- **Council of Europe:** **Resolution AP (89)1** “On the use of colorants in plastic materials coming into contact with food”, II, 2 (purity).

## Notes

### <sup>1</sup>Severe Metals Migration Testing in the Absence of Polymer Matrix:

Metal migration testing from pigment was performed following the principals of EN 13130:2004; however, in the absence of a polymer matrix. Briefly, the pigment to food simulant concentration was calculated using the prescribed plastic article surface area to food simulant ratio of 6 dm<sup>2</sup> to 1000 ml food simulant and the standard assumption that migration comes from the first 0.25 mm of the surface of said article. For this calculation, a mass fraction loading of 25% was used for the pigment content. Testing was performed using conditions considered as severe for complying to any time and temperature specification (4h at 100 °C followed by 10 days at 60 °C) in 3% acetic acid. The results from this method are typically much higher versus tests performed in non-polar polymers (LDPE) and typically in the range order of magnitude greater than similar testing results obtained from studies performed in polar polymers that swell in the 3% acetic acid food simulant for the same time/temperature regime (e.g., polyacrylamide).

**Table 1. Comparison of Al migration data for the method above versus standard testing protocols**

Test item	TiO <sub>2</sub> pigment (no polymer)	25% TiO <sub>2</sub> in LDPE	25% TiO <sub>2</sub> in Polyacrylamide	25% TiO <sub>2</sub> in Polyacrylamide
Conditions	4 h at 100 °C followed by 10 days at 60 °C	4 h at 100 °C followed by 10 days at 60 °C	4 h at 100 °C followed by 10 days at 60 °C	4 h at 100 °C
Food simulant	3% Acetic acid	3% Acetic acid	3% Acetic acid	3% Acetic acid
Al migration	57 mg/kg food	0,066 mg/kg food	>1 mg/kg food	0,64 mg/kg food

## End-Use Testing

Manufacturers using the above products for the fabrication of plastic materials and articles intended to come into contact with food, must comply with the general principles or regulatory requirement that these materials and articles should not, by reason of their coloration, pose a risk to human health or bring about either a deterioration in the organoleptic characteristics or other unacceptable changes to the food which they come into contact with. Colorants should be sufficiently integrated within the plastic materials and articles so as to preclude any significant migration into foodstuffs under normal conditions of use, as determined by an appropriate migration test methods outlined in:

- Annex III and V of regulation EC n° 10/2011; and/or
- Annex 4 of DFI Swiss Ordinance 817.023.21

The present review only refers to food-contact applications.

Ti-Pure™ products may not be directly added to food, pharmaceuticals, cosmetics, or cigarette papers/filters for tobacco products. Ti-Pure™ products may not be used in the manufacture of any medical device for implantation in the human body without prior written agreement of Chemours.

Further questions should be directed to [TiO2ProductStewardship@chemours.com](mailto:TiO2ProductStewardship@chemours.com)

**CAUTION:** Do not use or resell Chemours™ materials in medical applications involving implantation in the human body or contact with internal body fluids or tissues unless agreed to by Seller in a written agreement covering such use. For further information, please contact your Chemours representative. These products may not be directly added to food, pharmaceuticals, cosmetics, or cigarette papers/filters for tobacco products.

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