



# 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 BV, hereby declares that the composition of our products identified as:

#### Ti-Pure™ Titanium Dioxide Pigments for Plastics

##### Grade: R-350

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.

**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)

For R-350 the migration of Annex II substances are below the listed SML's in accordance with migration testing performed directly on pigment under severe testing conditions (3% acetic acid food simulant, 4 hours at 100 °C followed by 10 days at 60 °C, no polymer matrix)<sup>1</sup>.

As these are tests performed directly on pigment, they are highly precautionary.

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*

## 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, as last amended on April 26<sup>th</sup> 2022, Chapter I Plastics & XI Colorants and pigments. Section 3 (Purity criteria on pigment/colorants) section 4.a ( requirements for the pigmented end product ): for comments on migration of elements, see info on Commission Regulation 10/2011/EU under **General restriction outlined in Annex II (as last updated by EU 2020/1245) and <sup>1</sup>Severe Metals Migration Testing in the Absence of Polymer Matrix**

**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, as amended and last updated on Dec. 1<sup>st</sup> 2020, 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 and general restriction outlined in Annex 2 Section 2.3.1.

*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 and Sweden.**

**Council of Europe:** The above products, as supplied, comply with **Resolution AP (89)1** “On the use of colorants in plastic materials coming into contact with food”, including the purity criteria outlined in section II, 2 in the appendix to the Resolution.

**UK:** Statutory Instrument 2012 No. 2619: The Materials and Articles in Contact with Food (England) Regulations 2012, updated by statutory instrument 2019 No. 704 (European Union Exit regulations)

## 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 (4 hours 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 regiment (e.g., polyacrylamide).

### 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 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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