



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-103

has 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, including the amendments introduced by Commission Regulation (EU) 2025/351.

Colorants in accordance with Article 5.2(b) and Article 6(2) are not required to be listed in the Union list of authorized 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 and restrictions:

Overall Migration Limit (OML): 10 mg/dm² (Article 12)

Specific Migration Limits (SML): See Table 1.

Table 1. Specific Migration Limits (SML) of Constituents.

FCM Substance No.	Use as additive or polymer production aid (yes/no)	SML (mg/kg)	Restrictions and specifications
141	yes	6	None
1077	yes	-	Only to be used at up to 25,0% w/w, including in the nanoform

Note 1: Migration test for substance 141 (with an SML) in low density polyethylene (LDPE) and polypropylene (PP) samples at a loading of up to 24% pigment to polymer have shown the SML was met.

Note 2: FCM 1077 carries following note on verification of compliance: 'When used in polar polymers which swell in contact with foods for which simulant B is assigned in Annex III, there is a risk that under severe contact conditions the migration limits for aluminum and fluoride are exceeded. Under contact conditions above 4 hours at 100 °C this exceedance can be high.'

In addition, see important information on trimethylolpropane (TMP)¹

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 aluminum, 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).

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 as indicated in Table 2² and further detailed in the EFSA opinion for FCM 1077³.

This pigment has been approved for use as an additive up to 25% w/w in polymers in contact with all food types for any time and temperature conditions. However,

uses in polar polymers swelling in contact with food stuffs simulated by 3% acetic acid should be limited to conditions simulated by food contact up to 4 hours at 100 °C³.

Hence, we advise that plastic materials and articles produced with this grade in polar polymers should be verified for compliance with the ionic aluminum migration limit of 1 mg/kg food and the migration of fluoride of 0.15 mg/kg food.

In accordance with Article 3a, Article 8 and Annex IV of Regulation (EU) No 10/2011, as amended by Commission Regulation (EU) 2025/351, the Ti-Pure™ titanium dioxide pigments listed in this declaration are manufactured with a high degree of purity. Any non intentionally added substances originating from these pigments are limited to trace level impurities that are controlled by Chemours' raw material and process specifications. Based on the composition of the pigments, their low solubility and their use as additives immobilized within polymer matrices, such NIAS are not expected, when the pigments are used in accordance with this declaration and good manufacturing practice, to cause the final plastic material or article to fail to comply with Article 3 of Regulation (EC) No 1935/2004. It remains the responsibility of the manufacturer of the finished plastic materials and articles to assess NIAS arising from all formulation components and processing steps and to ensure compliance of the final article with the applicable food contact legislation.

There are no known sources of Primary Aromatic Amines 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

Only to be used at up to 25,0 % w/w in polymer. Uses in polar polymers, swelling in contact with food stuffs as simulated by 3% acetic acid, should be limited to conditions simulated by food contact up to 4 hours at 100

°C³.

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 1st 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 1st 2017, as last amended on April 26th 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 ²Severe 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. 1st 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/dm² or 60 mg/kg (food) (Article 12)

SML: See Table below.

Table 2. Specific Migration Limits (SML) of Constituents

FCM Substance No.	Use as additive or polymer production aid (yes/no)	SML (mg/kg)	Restrictions and specifications
95	yes	6	None

Migration test for substance 95 (with an SML) in low density polyethylene (LDPE) and polypropylene (PP) samples at loading of up to 24% pigment to polymer have shown the SML was met.

In addition, see important information on trimethylolpropane (TMP)¹

The Above listed Ti-Pure™ pigments 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 R-103 pigments should be verified for compliance to the aluminum SML value specifically in polar polymers.

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

¹Important information about TMP surface treated grades:

Chemours uses trimethylolpropane (TMP) as a surface treatment on Ti-Pure™ grade R-103, at levels up to 0.45 wt. % on a dry TiO₂ basis. Trimethylolpropane (TMP), has been self-classified as a "suspected reproductive toxicant (Rep. Tox. Cat. 2)" (H361f and H361d).



Furthermore, Chemours has completed an assessment of Ti-Pure™ grades of TiO₂ following the ILSI (International Life Sciences Institute Europe) best practices for food packaging value chains. In this assessment, it was observed that trace amounts of 2-Ethylacrolein may be generated as a result of degradation of TMP, which is used as a surface treatment on Ti-Pure™ R-103 product. A risk assessment in accordance with article 19 of Regulation (EC) No 10/2011 with due consideration of the worst-case scenario has concluded that the Ti-Pure™ product R-103 is compliant with Article 3 of Regulation (EC) No 1935/2004 and materials or articles made with it are safe for use with maximum loading levels up to 10 wt. % in the final product.

²Severe Metals Migration Testing in the Absence of Polymer Matrix

Metal migration testing from pigment was performed following the principles 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 dm² to 1000ml 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 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 3. Ionic Aluminum migration as determined from pigment and pigmented polymer compounds

Test Item	TiO ₂ pigment (No Polymer)	25% TiO ₂ in LDPE	25% TiO ₂ in Polyacrylamide	25% TiO ₂ in Polyacrylamide
Conditions	4 hours at 100°C followed by 10 days at 60°C	4 hours at 100°C followed by 10 days at 60°C	4 hours at 100°C followed by 10 days at 60°C	4 hours 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

Note: Migration is an order of magnitude greater in the absence of a polymer matrix.

³EFSA Panel on Food Contact Materials, Enzymes, and Processing Aids, Scientific Opinion

EFSA CEP Panel, "Safety assessment of the substance, titanium dioxide surface treated with fluoride-modified alumina, for use in food contact materials" EFSA Journal, 17(6): 5737. Adopted 22 May 2019. doi: 10.2903/j.efsa.2019.5737

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

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 Chemours in a written agreement covering such use. For further information, please contact your Chemours representative. These materials may not be directly added to food, pharmaceuticals, cosmetics, or cigarette papers or filters for tobacco products.

The foregoing applies solely to direct addition. This statement does not address, and should not be interpreted as determining, the suitability of Chemours products for use as components of materials or articles intended to come into contact with food. Where such uses are contemplated, the customer or other downstream user is solely responsible for determining and ensuring that the finished material or article complies with all applicable food contact laws and regulations in the relevant jurisdiction(s), including any applicable use, migration limits, good manufacturing practice requirements, and documentation or declaration obligations.

For medical emergencies, spills, or other critical situations, call +1 844 773 2436 for those within the United States or Canada. For those calling from other countries, call +1 302 773 1000, using the appropriate international access prefix. If immediate assistance is required, contact local emergency services.

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