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Ti-Pure™
Titanium Dioxide

EU Statement of Compliance for Food Contact Materials for Coatings

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 Coatings

Grades: R-900, R-960, and TS-6706

Color Index Name: White 6.

Color Index Number: 77891

have the following status relative to food contact regulations in Europe:

European Union

Ti-Pure™ titanium dioxide pigments grades are produced according to our quality management system, which complies with the requirements of the Regulation (EC) nº 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) nº 2023/2006, the above listed Ti-Pure™ titanium dioxide pigments comply with Regulation (EC) nº 1935/2004 as amended, and can be used in the countries of the European Union for the manufacturing of materials and articles according to article 3 of Regulation (EC) nº 1935/2004.

In absence of EU harmonised legislation for coatings foreseen to come into contact with food, the existing material specific legislation in the different EU Member states applies. An overview of the EU Member State legislation is shown below:

European Legislation

Comply with the following regulatory requirements:

Germany: "BfR Empfehlung" (BfR recommendations) IX purity of colorants for plastics other polymers used in commodities; (purity criteria), dated June 1st 2019

Netherlands: "Commodities Act (Packaging and Utensils Decree)" of Jan 1st 2017, as last amended on April 26th 2022, Chapter X Coatings & XI Colorants and pigments. Section 3 (Purity criteria on pigment/colorants), section 4.a (requirements for the pigmented end product):

Except for aluminum, none of the elements listed in section 4.a are intentionally added, but trace amounts of certain elements may be present.

With the exception of ionic aluminum, section 4.a substances are below the listed SML's (except for Hg where the LOQ is 0,01 mg/kg) 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)[1].

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[1].

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.

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Hence we advice that 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.

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 printing inks outlined in Chapter 12, annex 10 (List of permitted substances for the production of packging inks, and related requirements). Annex 10:
  - Titanium dioxide is listed under substance nr.2217, column 5: use as a pigment (C) and additive (AD), column 6: classification of the substance - part A.
  - Remark: In line with section 1.3.2. Definitions and explanations relating to lists I-V of column 5, additives used in the production of pigments do not require to be listed.
- The provisions applicable to coatings and varnishes outlined in Chapter 13a, annex 13:
  - Following substances are not intentionally added , not tested for but to the best of our knowledge not believed present: BADGE, BFDGE, NOGE, BPA

In accordance with the principle of mutual recognition as outlined in Art.34 – 36 of the Treaty on the functioning of the European Union (TFEU), the incomplete compliance of a product with legislation in one EU member state, does still allow the product to be placed on the market in the European Union on the basis of its full compliance in at least one Member State of the European Union.

As a consequence, compliance is granted in the following countries which do not have additional positive lists of substances: **Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, France, Finland, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and Norway.**

Council of Europe: Resolution AP (2004)1 "Coatings intended to come into contact with foodstuffs", Technical Document No. 1, List 1 of additives covers titanium dioxide as well as the substances used in coatings on pigments.

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)

Additional information

Specification of Use

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

Future Harmonized Legislation

Chemours intends to take all action required to have all relevant constituents of above mentioned Ti-Pure™ products covered by appropriate EU positive lists when harmonized legislation is promulgated.

Notes

[1]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^2 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).

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

End-Use Testing

Manufacturers using the above products for the fabrication of coatings 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 coatings materials and articles so as to preclude migration into foodstuffs under normal conditions of use, as determined by an appropriate method.

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 Ti02ProductStewardship@chemours.com