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To Whom it may concern

Geneva, 15 December 2008

REGULATORY COMPLIANCE STATEMENT FOR FOOD-CONTACT MATERIALS AND ARTICLES

We, **Du Pont de Nemours International S.A.**, hereby declare that the composition of our products identified as:

TI-PURE[®] Titanium dioxide pigments

Grades: **R-101, R-102, R-103, R-104, R-105, R-108,
R-350, R-706, R-900, R-902, R-902+, R-960, and TS-6200**

Color Index Name: White 6. Color Index Number: 77891.

Are produced according to our quality management systems which have been set up as required by the Regulation (EC) n° 2023/2006 on GMP for materials and articles intended to come into contact with food.

Comply with the following regulatory requirements:

- **Austria:** "Farbenverordnung" (Ordinance on colorants), RGB1. Nr. 142/1906, Art. 10, as amended / purity of colorants for plastics and paper.
- **Belgium:** "Koninklijk besluit/Arrêté royal" (Royal Decree) of 11 May 1992, Annex 1, Chapter VII, point 1 / purity of colourants for plastics.
- **France:** Circulaire No. 176 of 2 December 1959, as amended / purity of colorants for plastics. Titanium dioxide (TiO₂) is covered in the positive list in this Circulaire under No. 97.

This statement is based on our current knowledge of the subject and on technical data that DuPont believes to be reliable. However, DuPont makes no warranties express or implied as to its accuracy or sufficiency. It is intended for use, at their own risk, by persons qualified to determine for themselves the suitability of our products for particular purposes. The user should take the necessary additional measures to ensure that uses of our products and its own products comply with all applicable regulatory requirements.

- **Germany:** "BfR Empfehlung" (BfR recommendations, previously BgVV recommendations) IX / purity of colorants for plastics; XXXVI / colorants for paper and board.
- **Italy:** "Decreto Ministeriale" (= Ministerial Decree) of 21 March 1973, Art. 12 / purity of colorants for plastics) and Art. 31 / purity of colorants for paper and board), as amended.
- **Netherlands:** "VGB (Warenwet)" (Packaging and Utensils Decree) of 1 October 1979, Aa, I, 4 /purity of colorants for plastics and Aa, II,1.2.2.g / purity of colorants for paper and board.
- **Spain:** "Resolución" of 4 November 1982, Anexo 3 / purity of colorants for plastics.
- **Switzerland:** "Ordonnance du FDI sur les objets et matériaux" of 23 November 2005, Annexe 1.III.9 Pigments et matière colorantes (Pigments and Colorants (Purity Criteria))
- **Denmark, Finland, Greece, Ireland, Luxembourg, Norway, Portugal, Sweden and United Kingdom:** General regulatory requirement of 'no migration into food which could endanger human health'.
- **European Union:** Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs. Colorants are not yet specifically covered, however titanium dioxide, as well as the main substances used in Ti-Pure[®] pigments coatings do already appear in the Annex II, Section A: "List of authorized monomers and other starting substances or in the Annex III: "Incomplete list of additives which may be used...." of Directive 2002/72/EC, as further amended.

DuPont™ intends to take all action required to have all relevant constituents of above mentioned **Ti-Pure[®]** products covered by appropriate EU positive lists.

- **Council of Europe:**
 - Resolution AP (89) 1 "On the use of colorants in plastic materials coming into contact with food", II, 2 (purity).
 - Resolution AP (96) 5 "On surface coatings intended to come into contact with foodstuffs", Appendix 2, List 1.1. and List 1.2. cover titanium dioxide, as well as the main substances used in Ti-Pure[®] pigments coatings.

The above resolutions were adopted by the governmental representatives of all the countries mentioned above, with the exceptions of Greece and Portugal. It recommends that concerned governments take into account in their national laws and regulations the principles and/or the analytical methods and/or the inventory lists set out in these resolutions.

- Resolution AP (2002) 1 "On paper and board materials and articles used intended to come into contact with foodstuffs" covers titanium dioxide, as well as the main substances used in Ti-Pure[®] pigments coatings.

- **USA:** FDA Regulation, as specified in attachment.

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Notes

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 method.

Council of Europe Resolution AP (89) 1 sets out the principles (Appendix II, 1.) and the testing methods relating to visible migration (Appendix III, 1.).

The present review only refers to food-contact applications.

Ti-Pure[®] products may not be directly added to food or pharmaceuticals and are not recommended for use in medical devices or cosmetic. It is the responsibility of the processor or the user to investigate the safety, suitability and regulatory compliance status of said applications. It is however DuPont's[™] policy that **Ti-Pure[®]** products must not be used in medical applications involving permanent implantation in the human body.



Nathalie Ginzburg
Regulatory Affairs Specialist
DuPont Titanium Technologies

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US FDA STATUS

Colorants for Polymers

Ti-Pure® grades R-101, R-102, R-103, R-104, R-105, R-108, R-350, and R-960 are acceptable for FDA indirect food contact uses, under 21 CFR 178.3297 (Colorants for Polymers). Ti-Pure® grades R-103, R-104, R-108, and R-350 are acceptable up to 25 weight percent maximum loading of TiO₂ to polymer content. R-101, R-102, R-105 and R-960 have no loading limitations.

Paper and Paperboard

Ti-Pure® RPS Vantage® is acceptable for FDA indirect food use as colorants under 21 CFR 176.170 and 21 CFR 176.180, without restriction on Conditions of Use (compliant for Conditions A-H) or Food Type (compliant for Food Types I - IX). In addition, this product may be used in contact with all types of foods (I – IX) as described in Table 1 of 21 CFR 176.170, under microwave susceptor conditions.

Resinous and Polymeric Coatings

Ti-Pure® grades R-706, R-900, R-902, R-902+, R-960 and TS-6200 are acceptable for use in coatings or ink formulations that require FDA indirect food contact status under 21 CFR 175.300 (Resinous and Polymeric Coatings).

Adhesives

Ti-Pure® grades R-101, R-102, R-103, R-104, R-105, R-108, R-350, R-706, R-900, R-902, R-902+, R-942, and R-960 are acceptable for FDA indirect food contact uses under 21 CFR 175.105 (Adhesives). Ti-Pure® grades R-103, R-104, R-108, and R-350 are acceptable up to 25 weight percent maximum loading of TiO₂ to polymer content. R-101, R-102, R-105, R-706, R-900, R-902, R-902+, R-942 and R-960 have no loading limitations.

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