



# REGULATORY DATA SHEET

(TITANIUM DIOXIDE OIL)

17 May 2021

## 1. Product Identification

Composition

<i>Chemical Name</i>	<i>CAS number</i>	<i>EC Number</i>	<i>Amount (%) approx.</i>
Titanium dioxide	13463-67-7	236-675-5	99 %

Product description

Pigmentary titanium dioxide.  
Please refer to the technical data sheet or specifications for further information.

Country of production

Germany

Manufacturer

Venator Germany GmbH,  
Dr.-Rudolf-Sachtleben-Str. 4,  
D-47198 Duisburg, Germany

Origin of the product

Mineral

Harmonized Customs Tariff Code (HS Code)

28230000

## 2. SDS and Inventories

Safety Data Sheet available

Yes

Classification according to CLP/GHS

Not classified

IARC Classification

2B

C.I. (Colour Index)

77891

C.I. (Colour Index)

Pigment White 6

### 2.1. Global National Inventories

The product/its components are listed or exempt from listing in the following inventories<sup>1</sup>:

<i>Titanium Dioxide</i>				
<i>Country - Inventory</i>	<i>Yes</i>	<i>No</i>	<i>Exempt</i>	<i>Number</i>
Europe - EINECS	X			236-675-5
USA - TSCA	X			13463-67-7
Canada - DSL/NDSL	X			13463-67-7
Australia - AICS	X			13463-67-7
China - IECSC	X			13463-67-7

Japan - ENCS/MITI	X			1-558
Korea - KECL	X			KE-33900
Philippines - PICCS	X			13463-67-7
New Zealand - NZIoC	X			13463-67-7
Taiwan - TCSI	X			13463-67-7

## 2.2. EC regulation No 1907/2006 (REACH)- Registration:

All substances that are subject to Title II of the EC regulation No 1907/2006 (REACH) and contained in the Product for all VENATOR titanium dioxide grades manufactured in, or imported into, the EEA by Venator Materials Corporation were pre-registered and have been successfully registered.

The issued registration numbers for titanium dioxide of relevance for CPF-products are as follows:

Venator Uerdingen GmbH	01-2119489379-17-0018
Venator Germany GmbH	01-2119489379-17-0005
Venator P&A Finland Oy	01-2119489379-17-0006

The registration of titanium dioxide pigments covers between others grades.

All products supplied from outside the EEA are subject to REACH only if exported into the EEA. The importer of the products must comply with REACH for each imported substance.

### 2.2.1. Confirmation on Substances of Concern

Based on the knowledge of the raw materials and the manufacturing process we confirm that, apart from ubiquitous traces, none of the substances

- of the Candidate List of Substances of Very High Concern (SVHC) for authorisation are ingredients (> 0.1% w/w), or
- listed in ANNEX XIV and ANNEX XVII of (EU) 1907/2006 (REACH) are ingredients, or

have been intentionally introduced into the production process. These substances may only be present as ubiquitous trace impurities – in amounts not expected to exceed the allowable concentrations of the referenced document. (Validity: ECHA website / date of this letter)

\*Under various environmental protection and product safety regulations, directives, standards and initiatives “intentionally introduced” means “deliberately utilised during the manufacture of the components and/or for the formulation of a material or component where its continued presence is desired in the final product to provide a specific property, appearance or quality.”

### 3. Trace Metals

The following indications on trace metals are typical values and not valid specifications. The purity of Titanium Dioxide Oil is according to EP, USP, JP, FDA and E171 requirements

Elements	Titanium Dioxide Oil
Soluble Barium compounds	According to EP
Antimony (Sb) (HCl-soluble)	< 1
Arsenic (As) (HCl- soluble)	< 1
Cadmium (Cd) (total)	< 1
Lead (Pb) (total)	< 10
Chromium (Cr) (total)	< 5
Mercury (Hg) (total)	< 1
Nickel (Ni) (total)	< 1
Selenium (Se) (total)	< 1
Zinc (Zn) (total)	< 5

### 4. Materials of Concern

During the manufacture of Titanium Dioxide Oil, we do not intentionally<sup>2</sup> introduce substances specified under the below lists, regulations or conventions as of the date of this statement. These substances may only be present as ubiquitous trace impurities – in amounts not expected to exceed the allowable concentrations of the referenced document. Analyses for trace impurities in the products are not conducted as part of routine lot certification procedures.

- REACH – Candidate List of Substances of Very High Concern for authorisation – <https://echa.europa.eu/web/guest/candidate-list-table>
- REACH – Annex XIV (“Authorisation List”) – <https://echa.europa.eu/authorisation-list>
- REACH – Annex XVII (“Substances restricted under REACH”) including the previous legislation, Directive 76/769/EEC – <https://echa.europa.eu/substances-restricted-under-reach>
- Carcinogenic, mutagenic, teratogenic, persistent / bioaccumulative / toxic substances (PBT) or very persistent / very bioaccumulative substances (vPvB) under Regulation EC 1272/2008
- Ozone depleting substances (ODS) as under Montreal protocol and European Regulation EC 1005/2009 –  
<https://ozone.unep.org/treaties/montreal-protocol>  
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1005>
- Persistent Organic Pollutants (POPs) as under Stockholm Convention and European Regulation EC 850/2004 –  
<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0850:EN:NOT>  
<http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx>
- Volatile Organic Compounds (VOCs) according to definitions under “Ordinance on the Incentive Tax on Volatile Organic Compounds 814.018 – 12 November 1997”, the European Directive 2004/42/CE, the European Directive 2010/75/EU and Section 111 of the Clean Air Act (40CFR part 50.100)

- Allergens as under:
  - European Regulation EU 1169/2011 on provision of food information to consumer Annex II
  - US Food Allergen Labelling and Consumer Protection Act of 2004 (FALCPA) (Public Law 108-282) and associated allergen lists
  - FAO/WHO Food Standards Codex Alimentarius – CODEX STAN 1-1985 (REV2010)
  - Known allergens as listed in European Directive 2003/15/EC European and included in Regulation (EU) N°1223/2009 on Cosmetics Annex III
  - Toys Directive 2009/48/EC Annex II
- Substances listed under the International Chemical Weapon Convention (CWC) – <http://www.opcw.org/>
- Import and export of certain hazardous chemicals as under Rotterdam Convention and European Regulation (EU) 649/2012 (PIC)
- Substances listed on the World Anti-Doping Agency (WADA) prohibited list – <https://www.wada-ama.org/en/prohibited-list>

Specific substances listed in the table below

Alkyl phenols (APs)	Nonylphenol ethoxylates (NPEOs)
Alkylphenolethoxylates (APEOs)	Nonylphenols (NPs)
Amines as listed in EU Directive 2002/61/EC	Novolac glycidyl ethers (NOGEs)
Azo colorants and compounds	Octylphenol ethoxylates (OPEOs)
Bisphenol A (BPA)	Octylphenols (OPs)
Bisphenol-a-diglycidyl ether (BADGE)	Organotin compounds
Bisphenol-f-diglycidyl ether (BFDGE)	Pentachlorophenol (PCP)
Dioxins	Perfluoro octanoic acid (PFOA)
Ethylene oxide	Perfluorooctane sulfonate (PFOS)
Fragrances as listed in Annex II Section III from EU Directive 2009/48/EC	Phthalates
Furans	Polycyclic aromatic hydrocarbons (PAHs)
Halogenorganic components (AOX)	Polyhalogen-biphenyl / terphenyl / diphenyl-ethers (PCBs, PBBs, PCTs, PBDE)
Latex or natural rubber	Primary aromatic amines (PAAs)
Parabenes	Asbestos like fibres
B-Lactames	Antibiotics
Hormones/Steroids	Pesticides
Fungicides	Vaccines

#### 4.1. Californian Proposition 65

Herewith we confirm that the following substances are known to the State of California to cause cancer as listed under Proposition 65 State Drinking Water and Enforcement Act:

Titanium dioxide [airborne, unbound (CAS# 13463-67-7)

Technically unavoidable impurities are also listed: Arsenic (As), Cadmium (Cd), Chromium VI (Cr<sup>6+</sup>), Cobalt (Co), Lead (Pb), Mercury (Hg) and Nickel (Ni). For indication on levels see above.

More information explaining the background and implications of titanium dioxide listing is given on TDMA website. <https://tdma.info/can-titanium-dioxide-cause-cancer/>

#### 4.2. German Wassergefährdungsklasse WGK class

The Product belongs to: nwg - not hazardous for water

### 5. Food Contact Status

#### 5.1. EU Food Contact Status

For colorants used in plastic materials and articles, compliance with Article 3 of the Framework Regulation (EC) No 1935/2004 must be assessed in accordance with internationally recognised scientific principles on risk assessment according to Article 19 Commission Regulation (EU) No. 10/2011.

According to Article 5.2 (b) of Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food, as amended (the Plastics Regulation), colorants and their components are not regulated as additives under this Regulation and thus are not required to be listed in the Union list of authorised substances. Article 6.2 of Regulation (EU) No. 10/2011 further provides that colorants may be used in the manufacture of plastic layers in plastic materials and articles subject to national law.

We hereby confirm that the product, used as a colorant in plastics, coatings or inks materials complies with specific measures on colorants of the following national laws or recommendations:<sup>3</sup>

- |                 |  |
|-----------------|--|
| Europe:         | Council of Europe Resolution AP(89) 1 on the use of colorants in plastic materials coming into contact with food; 13.9.1989  |
| Czech Republic: | Príloha c. 1 k vyhlášce c. 38/2001 Sb., 19.01.2001   |
| Germany:        | Bundesinstitut für Risikobewertung, Empfehlung IX (Farbmittel zum Einfärben von Kunststoffen und anderen Polymeren für Bedarfsgegenstände, Stand: 01.02.2015) <sup>4</sup><br>XXXVI (Papiere, Kartons und Pappen für den Lebensmittelkontakt),<br>XXXVI-1 (Koch- und Heißfilterpapiere und Filterschichten),<br>XXXVI-2 (Papiere, Kartons und Pappen für Backzwecke),<br>LII (Füllstoffe) Stand: 01.07.2016)   |
| Belgium:        | Annexe I, VII(1) of Arrêté Royal du 11 mai 1992 - Moniteur Belge du 24.07.92, p 16719  |
| UK:             | BPF/BIBRA Code of Practice for food contact applications   |
| Spain:          | Annex II of Real Decreto 847/2011, de 17 de junio, por el que se establece la lista positiva de sustancias permitidas para la fabricación de materiales poliméricos destinados a entrar en contacto con los alimentos (B.O. del E Num 164, 11.07.2011)   |
| France:         | Circulaire N°176, 2.12.1959 - Brochure N°1227 Edition 2002 (TiO <sub>2</sub> is listed as substance no. 97 in section C (mineral products) <sup>5</sup>  |
| Italy:          | Article 12, Chapter I of Title II of Decreto Ministeriale del 21/03/1973 Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale. emanato/a da : Ministro della Sanità e pubblicato/a su : Gazz. Uff. Suppl. Ordin. n° 104 del 20/04/1973, criteria as amended by Decreto Ministeriale 22 luglio 1998, n°338 - Gazzetta Ufficiale, n.228 dell'30 settembre 1998 |

- The Netherlands: Warenwetregeling verpakkingen en gebruiksartikelen (Warenwet,) STAATSCOURANT Nr. 8531 27.03. 2014, Deel A, Hoofdstuk XI – Kleurstoffen en pigmenten.
- Romania: ORDIN nr.869 din 17 iulie 2006 al ministrului sănătății publice privind aprobarea Normelor specifice referitoare la cauciucul care vine în contact cu alimentele și la cernelurile și concentratele de culoare ce intră în componența materialelor și obiectelor care vin în contact cu alimentele
- Switzerland: Annex 2 Table 3, N°8 of Ordonnance du DFI sur les matériaux et objets destinés à entrer en contact avec les denrées alimentaires - R.O. 2017 1537

We confirm that the quality of the Product meets the requirements of the above listed national laws or recommendations in terms of toxic metal/metalloids and organic impurities. Manufacturers using the Product for the fabrication of plastic materials and articles intended to come into contact with food, must ensure that the colorant is sufficiently integrated within the plastic materials and articles so as to preclude any visible migration into foodstuffs under normal conditions of use, as determined by appropriate testing methods.<sup>6</sup>

SML and/or other specifications/restrictions according to Annex II of Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food have to be tested in general and do not need to be mentioned separately.

#### **5.1.1. Dual use additive**

Concerning Article 11(3) of the Plastics Regulation, titanium dioxide as a chemical species is listed in Annex II (Union list of food additives approved for use in food and conditions of use) as authorised food additives in Regulation (EC) No 1333/2008 on food additives and subsequent amendments published as of to the date of this letter. Titanium dioxide, E-No. 171, is permitted in general in foodstuffs in quantum satis. Because titanium dioxide is a highly insoluble substance, there is no reason why when included in a plastic layer, it would migrate into the food. Titanium dioxide corresponding to purity criteria E171 used to colour foodstuffs is technically unsuitable for colouring plastics.

#### **5.1.2. Regulation (EC) No 2023/2006 (GMP)**

The manufacture of the starting substance is excluded from the scope of Commission Regulation (EC) No 2023/2006 and hence GMP (Good Manufacturing Process) rules do not apply to our titanium dioxide pigments.

Venator Materials Corporation operate a quality management system, which complies with the requirements of ISO 9001/2008.

Electronic copies of our certificates can be downloaded as a pdf file from following internet link: <http://www.venatorcorp.com/products-and-applications/quality-and-safety/ehs-and-quality-certificates>

#### **5.1.3. Regulation (EC) No 1935/2004 – Article 17 (Traceability)**

Business systems and procedures are implemented as part of ISO 9001/2008 to fulfil the requirements of Article 17 of Regulation (EC) No 1935/2004.

#### **5.1.4. Downstream Business Operator Responsibilities**

**In addition to the above assessments that indicates that the Product would not present a human health or safety risk when used as a colorant in the manufacture of plastic layers in plastic materials and articles intended to come into contact with food, it is the responsibility of the manufacturer of the finished article and the filler to ensure that materials and articles, which in their finished state, are intended to be brought into contact with foodstuffs or are brought into contact with foodstuffs, must not transfer any components to the packed foodstuff in quantities that could endanger human health, or bring about an unacceptable change in the composition or deterioration in organoleptic properties.**

**We would like to draw your attention to the fact that the information concerning the nature/content of the surface treatment is confidential and must not be disclosed or provided**

to anyone within your Company not concerned by regulatory affairs and outside your Company without prior consent of Venator Materials Corporation. In providing this information, we however authorise your Company to supply it:

- to competent authorities, including to support the premarket approval of products
- outside your Company as part of a written declaration of compliance as foreseen in Article 15 of European Regulation (EU) No 10/2011.
- provided it is done in such a way that the information cannot be directly linked to the commercial name of the Product.
- Disclosure of this information to third parties that causes intentional or unintentional competitive damage to Venator will be vigorously pursued.

## 5.2. USA FDA Food Contact Status

Titanium dioxide as a chemical species is either prior-sanctioned under 21 CFR 181.30 for use in the manufacture of paper and paperboard products used in food packaging or listed in 21 CFR 178.3297 - Colorants for polymers. Titanium Dioxide Oil may also be used under the following 21 CFR parts:

### 175: INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

175.105 - Adhesives.

175.210 - Acrylate ester copolymer coating.

175.300 - Resinous and polymeric coatings.

### 176: INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

176.170 - Components of paper and paperboard in contact with aqueous and fatty foods.

176.180 - Components of paper and paperboard in contact with dry food.

### 177: INDIRECT FOOD ADDITIVES: POLYMERS

177.1200 - Cellophane.

177.1650 - Polysulfide polymer-polyepoxy resins.

177.2260 - Filters, resin-bonded.

177.2355 - Mineral reinforced nylon resins.

177.2600 - Rubber articles intended for repeated use.

177.2800 - Textiles and textile fibers.

### 178: INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

178.3297 - Colorants for polymers.

### 181: PRIOR-SANCTIONED FOOD INGREDIENTS

181.30 - Substances used in the manufacture of paper and paperboard products used in food packaging.

The existence of the food contact notification does not relieve use of the food contact substance from compliance with general provisions applicable to indirect food additives. For example, in accordance with section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act, use of the food contact substance should not impart odor or taste to food rendering it unfit for human consumption.

## 5.3. GB9685-2016 Status

With regard to the Chinese regulation “Hygienic standards for uses of additives in food containers and packaging material – GB9685-2016” and its amendments, all ingredients in Titanium Dioxide Oil is listed in the GB9685-2016 positive list for use in:

- |             |                     |
|-------------|---------------------|
| - Plastics: | Dosage as necessary |
| - Adhesive: | Dosage as necessary |
| - Coating:  | Dosage as necessary |
| - Inks:     | Dosage as necessary |

It is responsibility of the manufacturer of the finished article and the filler to ensure that materials and articles, which in their finished state, are intended to be brought into contact with foodstuffs or are

brought into contact with foodstuffs, must not transfer any components to the packed foodstuff in quantities that could endanger human health, or bring about an unacceptable change in the composition or deterioration in organoleptic properties.

#### **5.4. MERCOSUR Status**

We confirm, that the quality of the Product, regarding limits of toxic metals/metalloids and organic impurities conforms to the requirements set forth under paragraph 2 of the annex of MERCOSUR/GMC/RES. N° 15/10 – “REGLAMENTO TÉCNICO MERCOSUR SOBRE COLORANTES EN ENVASES Y EQUIPAMIENTOS PLÁSTICOS DESTINADOS A ESTAR EN CONTACTO CON ALIMENTOS (DEROGACIÓN DE LA RES. GMC N° 28/93)” adopted by Argentina, Brazil, Paraguay and Uruguay and implemented through:

- Argentina: Res. Conj. 27/2012 SPRel 21/2012 SAGyP of 30/1/2012 modifying Código Alimentario Argentino
- Brazil: Resolução RDC nº 52, de 26 de novembro de 2010
- Uruguay: MSP Decreto nº 218/014 of 30/07/14.

Manufacturers using the Product for the production of plastic materials and articles intended to come into contact with food must ensure that the pigment is sufficiently integrated within the plastic materials and articles so as to preclude any visible migration into foodstuffs under normal conditions of use and meet the criteria as set forth under paragraph 3 of the annex of MERCOSUR/GMC/RES N° 15/10 using appropriate testing methods.

It is responsibility of the manufacturer of the finished article and the filler to ensure that materials and articles, which in their finished state, are intended to be brought into contact with foodstuffs or are brought into contact with foodstuffs, must not transfer any components to the packed foodstuff in quantities that could endanger human health, or bring about an unacceptable change in the composition or deterioration in organoleptic properties.

## **6. Other Regulations**

### **6.1. EU Directive 94/62/EC and CONEG (packaging waste)**

The Product is not classified as dangerous under Regulation (EC) N° 1272/2008 (CLP/GHS) and their subsequent amendments.

We confirm, that for the Product, the sum concentration for lead, mercury, cadmium and hexavalent chromium does not exceed 100 part per million by weight according to limits set forth in article 11 of the European Directive 94/62/EC as amended by European directive 2005/20/EC and in CONEG regulation.

Note that the afore-mentioned directive and regulation apply to the packaging, and the Product supplied to you does not fall under that category but may be used to manufacture such packaging.

### **6.2. Directive 2011/65/EU (RoHS), Directive 2000/53/EC (ELV) and Directive 2012/19/EU (WEE)**

Herewith we confirm that for our manufacture of the Product we do not intentionally intentionally<sup>2</sup>:

the heavy metals cadmium (Cd), mercury (Hg), lead (Pb) or hexavalent chromium (Cr (VI+)), flame retardants polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE) and phthalates (DEHP, BBP, (DIBP)) listed in EC Directive 2000/53/EC (ELV) and annex II of Directive 2011/65/EU (RoHS) as amended by Directive (EU) 2015/863 or, as the case may be, the presence of these substances in our final Venator Product would not exceed the maximum tolerated concentrations mentioned in the annex II of the Directive.

the substances listed in Annex VII of the EC Directive 2012/19/EU of 4 July 2012 and amendments on waste electrical and electronic equipment (WEEE) as amended up to the date of this letter.



These substances may only be present as adventitious trace impurities (not intentionally added to the product) in amounts not normally expected to exceed the maximum allowable concentrations provided for in the above-mentioned directives. Analyses for trace impurities in the Product are not conducted as part of routine lot certification procedures.

Note that the afore-mentioned directives apply to electrical and electronic equipment and the Product supplied to you does not fall under that category but may be used to manufacture such equipment.

### **6.3. EN 71-3 (2013) – EU Directive 2009/48/EC (Safety of toys)**

In detail the compliance depends on application conditions. Therefore, a global compliance declaration is not viable. Responsibility for compliance testing remains solely with the natural or legal person who places articles in the market.

The Product is not classified as dangerous under Regulation (EC) N° 1272/2008 (CLP/GHS), i.e. not classified as CMR cat 1A, 1B, 2.

Herewith we confirm that for our manufacture of the product we do not intentionally introduce<sup>2</sup>:

- The following substances listed in Annex II, Part III “Chemical Properties” of EC Directive 2009/48/EC of 18<sup>th</sup> June 2009 and subsequent amendments on the safety of toys:
- Nitrosamines or nitrosable substances in point 8
- The allergenic fragrances in point 11
- The substances listed in Annex II, Appendix C of EC Directive 2009/48/EC for toys intended for use by children under 36 months or in other toys intended to be placed in the mouth as amended by Directives (EU) 2015/2115, (EU) 2015/2116 and (EU) 2015/2117.

We confirm that for the manufacture of the Product we do not intentionally introduce<sup>2</sup> substances based on Aluminium, Antimony, Arsenic, Barium, Boron, Cadmium, Chromium (III), Chromium (VI), Cobalt, Copper, Lead, Manganese, Mercury, Nickel, Selenium, Strontium, Tin, Organic Tin, Zinc as listed in Annex II, Part III “Chemical Properties” of EC Directive 2009/48/EC point 13 and European Standard EN 71-3:2013 on migration of certain elements. However, traces of these elements may be present as technically unavoidable impurities due to the ore used in the process.

In practice, titanium dioxide pigment is encapsulated during compounding by the customer, or is contained within inks or coatings, and is not directly available in unprocessed form to the consumer. Per the standard, final testing of the toy or toy component would be required to determine whether the matrix the titanium dioxide pigment is introduced into prevents migration of the elements above the allowable limit. Since migration values can be influenced during processing in toy production, the formerly common practice under EN 71-3: 1995, where the raw material manufacturer generally determines conformance with all values to the processor, is no longer workable under EN 71-3:2013. Customers are advised to test their final applications.

## **6.4. Cosmetic Regulations**

### **6.4.1. EU Regulation (EC) No. 1223/2009**

#### **6.4.1.1. INCI Composition**

The composition is given as a guide to help label a finished formulation and does not represent as specification. Please consult the relevant safety data sheet (SDS), technical data sheet (TDS) and certificate of analysis (CoA) for more detailed information.

INCI name\*/ Colour Index No: TITANIUM DIOXIDE / CI 77891

Chemical/IUPAC name: Titanium Dioxide

CAS No: 13463-67-7

Label content: 100%

Cosmetic Function: Colorant, Opacifier, UV-Filter

<sup>2</sup>according to Commission Decision 2006/257/EC establishing an inventory and a common nomenclature of ingredients employees in cosmetic products as amended under CosIng database: <http://ec.europa.eu/growth/tools-databases/cosing/>

Titanium Dioxide is listed in Annex IV of European Regulation (EU) No 1223/2009 under reference number 143 as colour allowed in cosmetic product without restriction on type of product or body part when complying with EU food color specification and in Annex VI of the regulation under the reference number 27 as UV-Filter allowed up to 25% in cosmetics.

We confirm that the product is manufactured to comply with the purity requirements of EU Food Color Specification E171 – European Regulation No 231/2012.

#### **6.4.1.2. Impurities and by products**

The product may include technically unavoidable residues of heavy metal/metalloids due to the process or minor by-products listed in Annex II of the regulation as amended to the date of this issue.

Antimony (Sb) ref. number 40, Arsenic (As) ref. number 43, Barium (Ba) ref. number 46, Cadmium (Cd) ref. number 68, Chromium Cr) ref. number 97, Lead (Pb) ref. number 289, Mercury (Hg) ref. number 221, Selenium (Se) ref. number 297, Zirconium (Zr) ref. number 391 and Nickel (Ni) ref. number 1093. For indication on levels see above.

We confirm that for the manufacture of the product, we do not intentionally introduce<sup>2</sup> substances reported under the following lists as amended to the date of this issue:

- CMR classified substances according to Regulation (EC) 1272/2008 (CLP)
- Any other substances listed in Annex II of the regulation
- Substances listed in Annex III of the regulation
- Substances listed in Annex V of the regulation

Therefore, we do not analyze the product for them.

Other impurities, including residual salts, may be referred to in the certificate of analysis (CoA). They are not typically additives and consequently they are not expected to significantly impact upon the risk assessment, but they do form an intrinsic part of the product which may be relevant to product quality, performance and/or the specification. As such information is not repeated here: please refer the CoA.

Note that the European Directive 2003/15/EC (cosmetic allergens) from February 27<sup>th</sup>, 2003 has subsequently been incorporated into Annex III of the Regulation (EC) No. 1223/2009 of the European Parliament and of the Council from November 30<sup>th</sup>, 2009 and so a separate statement is not given. Please refer to the statement on Annex III above.

#### **6.4.2. FDA Cosmetic Status**

Titanium Dioxide is part of the coloring color additives exempt from certification under 21 CFR 73.2575 for use in coloring cosmetic generally, including cosmetics applied in the area of the eye, in amounts consistent with good manufacturing practice. We confirm that the quality of the product meets the specification requirements set forth under 21 CFR 73.2575

#### **6.5. US Federal Right-to-Know Act reportable material**

The Product is not reportable under Sara Title III, Section 312 (Tier II), Sara Title III, Section 313 (Form RI) or CERCLA/SARA Hazardous Substance.

#### **6.6. Conflict Minerals – US-Dodd-Frank Wall Street Reform and Consumer Protection Act:**

For the manufacture of the Product we do not intentionally introduce any tin, tungsten, gold or tantalum, termed as "Conflict Minerals", and these are not necessary to the functionality or production of the Venator Product. Therefore, these Conflict Minerals are not expected to be present in the Venator Product and we do not analyse for those minerals – or as the case may be – they would only be present as technically unavoidable impurities.

## 7. Shelf Life and Storage

Safe handling and storage advices are given under section 7: Handling and Storage of the Safety Data Sheet.

Titanium Dioxide products in powder form are inert and stable and remain chemically unchanged for an indefinite period of time.

Since a definite expiry date or shelf life cannot be set, (from the chemistry point of view, colour, brightness and tone, etc.) nor do we have control of the storage/handling conditions at various stages of the supply chain, we give the following general instructions:

*“To achieve best possible results, store the product sealed in its original packaging, un-stacked in a suitable dry warehouse environment at normal temperatures and air humidity. Good stock rotation practice is encouraged using a FIFO (first in, first out) procedure and it is recommended that products are used within 36 months of delivery”.*

In the case of extended storage times of a material it is recommended:

- the product is tested successfully before use in full scale production
- extra care is paid to the dispersion processes to ensure good dispersibility

Please do not hesitate to contact your Venator representative, if you have any further questions.

Yours sincerely,

Global Product EHS Management

### Notes:

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<sup>1</sup> Food additives, drugs, cosmetics may be exempted from some of the inventories. Titanium Dioxide Oil may be used as such.

<sup>2</sup> Under various environmental protection and product safety regulations, directives, standards and initiatives “intentionally introduced” means “deliberately utilised during the manufacture of the components and/or for the formulation of a material or component where its continued presence is desired in the final product to provide a specific property, appearance or quality.” The above-referenced substance(s) is (are) not intentionally introduced as additives or used in the manufacturing process for

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the Venator Product. The substance(s) may only be present as adventitious trace impurities (not intentionally added to the product). Analyses for trace impurities in the Products are not conducted as part of routine lot certification procedures.

<sup>3</sup> Although Slovenia and Greece have purity requirements for colorants used in food contact materials, the Slovenian authorities have indicated that their purity requirements are old and not legally binding while the Greek authorities have confirmed that their purity requirements are out of date, and that it would be preferable to refer to the purity requirements set out in Council of Europe Resolution AP (89) 1 on colouring plastic materials coming into contact with food. Hence, we have not included references to the Slovenian and Greek legislative measures.

<sup>4</sup> In the 2015 BfR IX published version, the purity requirements for primary aromatic amines refer to a migration value which, per se, can be determined only in the end product. A binding confirmation towards the compliance of our products to purity requirements of BfR Recommendation IX in terms of primary aromatic amines can no longer be provided, however for the manufacture of the Product, we do not intentionally introduce any primary aromatic amines or azo compounds.

<sup>5</sup> This circulaire is to be deemed repealed given that it has not been published on the Prime Minister's website pursuant to Decree 2008-1281 of 8 December 2008, as amended, and therefore can no longer be considered to be legally binding. Nonetheless, it is a useful reference for the safety assessment of this product.

<sup>6</sup> Resolution AP(89)-1, appendix III,1. or 24. Mitteilung, Bundesgesundheitsbl. 15(1972) 285



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