

**PJSC SUMYKHIMPROM**  
**Safety Data Sheet**  
conforming to Regulation (EC) No. 1907/2006  
**titanium dioxide**



Date: 17.05.2021

Version: 2.7

Supersedes version: 2.6

### 1 IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1 Product identifier	
<b>Substance name</b>	titanium dioxide
<b>Trade name</b>	Titanium Dioxide pigmental, grades SumTITAN R-204, SumTITAN R-2041, SumTITAN R-206, SumTITAN R-2061, SumTITAN R-2071, SumTITAN R-208
<b>ES#</b>	236-675-5
<b>CAS name</b>	Titanium (IV)oxide
<b>CAS#</b>	13463-67-7
<b>Molecular formula</b>	O <sub>2</sub> Ti, TiO <sub>2</sub>
This substance is not classified according to Article 59 (10) of the REACH Regulation and Annex VI to Regulation (EC) No 1272/2008 (CLP).	
<b>REACH registration No</b>	01-2119489379-17-0029
1.2 Relevant identified uses of the substance or mixture and uses advised against	
<b>Identified uses</b>	Agents adsorbing and absorbing gases or liquids Colouring agents, pigments Fillers Intermediates Laboratory chemicals Odour agents Semiconductors and photovoltaic agents Photosensitive agents and other photo-chemicals Catalyst supports, delustrants
<b>Uses advised against</b>	none
1.3 Details of the supplier of the safety data sheet	
<b>Manufacturer</b>	Public Joint-Stock Company SUMYKHIMPROM Kharkivska str., Sumy, Ukraine, 40003
<b>Only Representative</b>	ZANGAS Hoch- und Tiefbau GmbH Polina Konstantinova Schwindgasse 5/1/4, Vienna, 1040, Austria, E-mail <a href="mailto:P.Konstantinova@zangasgroup.com">P.Konstantinova@zangasgroup.com</a> +43 1 274 16 366
<b>Responsible person</b>	Manufacturing Director Mr. O. V. Denschikov E-mail: <a href="mailto:stand@sumykhimprom.org.ua">stand@sumykhimprom.org.ua</a>
1.4 Emergency telephone number	
+38(0542) 683-550, +38 (0542) 674-260 – 24 hours	

### 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance		
Classification according to Regulation (EC) No 1272/2008 [CLP/GHS]	Self classification	Additional information
-	-	-
Human Health effects		
<b>Inhalation</b>	Inhalation of dust may cause discomfort. Inhalation exposure to large amounts may cause a temporary drying effect or irritation of mucous membranes. Exposure to dust may lead to aggravation of pre-existing upper respiratory and lung diseases.	
<b>Eyes</b>	Inert foreign body hazard	
<b>Skin</b>	Prolonged contact may result in scaling/irritations due to drying of	

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	the skin and/or mechanical abrasion related to skin-to-clothing contact or skin-to-skin contact.
<b>Swallowing</b>	The classification criteria according to regulation (EC) 1272/2008 as specific target organ toxicant (STOT) repeated exposure, oral are not met since no reversible or irreversible adverse health effects were observed immediately or delayed after exposure and the no observed adverse effect level (NOAEL) via oral application is above the guidance value for a Category 1 classification of 10 mg/kg bw/day and above the guidance value for a Category 2 classification of 100 mg/kg bw/day. For the reasons presented above, no classification for specific target organ toxicant (STOT) repeated exposure, oral is required.
<b>2.2 Label elements</b>	
<b>Product identifier</b>	titanium dioxide (TiO <sub>2</sub> ) EC Number: 236-675-5 CAS Number: 13463-67-7
<b>Hazard pictograms</b>	
<b>Signal word</b>	No signal word
<b>Hazard statements</b>	-
<b>Precautionary statements</b>	-
<b>2.3 Other hazards</b>	
none	

### 3 COMPOSITION/INFORMATION ON INGREDIENTS

<b>3.1 Substances</b>								
Chemical name	EC #	CAS #	Concentration, range %					
titanium (IV)oxide	236-675-5	13463-67-7	> 90.0 <= 100.0 % (w/w)					
<b>3.2 Surface treatment</b>								
Components content	CAS №	Classification CLP	Grade					
			R-204	R-2041	R-206	R-2061	R-2071	R-208
Aluminium compounds in terms of Al(OH) <sub>3</sub>	21645-51-2	none	+	+	+	+	+	+
Silicon compounds in terms of SiO <sub>2</sub>	60676-86-0	none	+	+	+	+	-	-
Water soluble matter in terms of Na <sub>2</sub> SO <sub>4</sub>	7757 - 82 - 6	none	+	+	+	+	+	+
Organic matter in terms of C, % by wt. (2,2',2''-nitrilotriethanol)	102-71-6	none	0,1	0,1	-	-	-	0,1
Organic matter in terms of C, % by wt. 1,1,1-Trimethylolpropane	77-99-6	Repr.2 H 361fd	-	-	-	-	0,1	-
Zirconium compounds in terms of ZrO <sub>2</sub>	1314-23-4	none	-	-	-	-	-	+

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#### 4 FIRST AID MEASURES

<b>4.1 Description of first aid measures</b>	
<b>General information</b>	Provide rest, warm conditions, comfortable position, fresh air availability, free air access. In case of sickness call for medical help
<b>4.2 Most important symptoms and effects, both acute and delayed</b>	
<b>In case of inhalation</b>	Take out to fresh air, rinse nasopharynx with drinking water.
<b>In case of eye contact</b>	Rinse with running tap water.
<b>In case of skin contact</b>	Take off and dispose of contaminated cloths, shoes, ammunition. Rinse with running tap water till the product complete removal.
<b>In case of ingestion</b>	Rinse the mouth thoroughly. Allow to drink plenty of water. In case of sickness call for medical help.
<b>Information to physician</b>	In case of ingestion :allow to drink plenty of water, take activated carbon, purgative.
<b>First aid arsenal</b>	Universal medical kit with a set of drugs (in consultation with the medical department of the enterprise).
<b>4.3 Indication of any immediate medical attention and special treatment needed</b>	
When exposed there is no need to seek immediate medical attention	

#### 5 FIRE-FIGHTING MEASURES

<b>5.1 Extinguishing media</b>	
<b>Suitable extinguishing media</b>	Use any means suitable for extinguishing surrounding fire
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams in case of large fire.
<b>5.2 Special hazards arising from the substance or mixture</b>	
<b>Hazardous combustion products</b>	none
<b>Special protective equipment for fire-fighters</b>	As in any fire, wear a self-contained breathing apparatus in pressure demand, MSHA/NIOSH (approved or equivalent), and full protective gear.
<b>Advice for fire-fighters</b>	Use extinguishing media appropriate for surrounding fire.
<b>Additional information</b>	-

#### 6 ACCIDENTAL RELEASE MEASURES

<b>6.1. Personal precautions, protective equipment and emergency procedures</b>	
<b>Personal precautions</b>	Avoid dust formation. Use personal protection means as stated in the section 8.
<b>Emergency procedures</b>	Collect in dry manner, avoid dust formation.
<b>6.2 Environmental precautions</b>	
Prevent dust dispersal into environment. Prevent the product ingress into surface and soil waters.	
<b>6.3 Methods and material for containment and cleaning up</b>	
Use valid mechanical means of cleaning (vacuum, sweeping).	
<b>6.4 Reference to other section</b>	
No dangerous substances are released. See Section 7 for safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.	

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## 7 HANDLING AND STORAGE

7.1 Precautions for safe handling	
<b>Precautions for safe handling</b>	Avoid aerosol formation when handling. Apply respiratory organs, eyes and skin individual protection means. Premises mechanical ventilation, utilization of dust and gas purifying equipment, equipment in pressurized version. In the event of casual substance discharge: collect in dry manner into container, equipped with cover and marking, avoid dust formation. Contaminated surface should be washed with water with detergents.
<b>Fire preventions</b>	None, as product has no flammable properties. See section 5.
<b>Aerosol and dust generation preventions</b>	Use local exhaust ventilation or other appropriate engineering controls to maintain exposures below occupational exposure limit.
<b>Electrostatics prevention</b>	As a matter of good practice take measures to prevent the build up of electrostatic charge, such as ensuring all equipment is electrically grounded.
<b>Safe transporting</b>	Adhere to the rules on the transport of goods, which operate for the appropriate type of transport. Not violate the integrity of container. During loading works execute instructions and rules for the appropriate works.
<b>Advice on general occupational hygiene</b>	Do not eat, drink and smoke in work areas, wash hands after use, remove contaminated clothing and protective equipment before entering eating areas.
7.2 Conditions for safe storage, including any incompatibilities	
<b>Technical measures and storage conditions</b>	Store in manufacturer's package in dry area where it is safe from contamination and exposure to rain, snow and subsoil water.
<b>Packaging materials</b>	Package should exclude moisture penetration and guarantee the safety of the product during transportation and storage.
<b>Requirements for storage rooms and vessels</b>	Special requirements for storage structures are not established. Protect from moisture.
7.3 Specific end use(s)	
none	

## 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters		
Occupational exposure limits		
Chemical Name	Country	OEL
Titanium Dioxide	United Kingdom	STEL: 30 g/m <sup>3</sup> STEL: 12 mg/m <sup>3</sup> TWA: 10 mg/m <sup>3</sup> TWA: 4 mg/m <sup>3</sup>
	France	VME: 10 mg/m <sup>3</sup>
	Spain	VLA-ED: 10mg/m <sup>3</sup>

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Portugal	TWA: 10 mg/m <sup>3</sup>
The Netherlands	MAC:10 mg/m <sup>3</sup>
Denmark	TWA: 6 mg/m <sup>3</sup>
Austria	STEL: 10 mg/m <sup>3</sup> MAK: 5 mg/m <sup>3</sup>
Switzerland	MAK: 3 mg/m <sup>3</sup>
Poland	NDS: 10.0 mg/m <sup>3</sup>
Norway	TWA: 5 mg/m <sup>3</sup> STEL: 10 mg/m <sup>3</sup>
Ireland	TWA: 10 mg/m <sup>3</sup> (respirable fraction)
Belgium	TWA: 10 mg/m <sup>3</sup>
Greece	TWA: 10 mg/m <sup>3</sup> TWA: 5 mg/m <sup>3</sup>
Sweden	5 mg/m <sup>3</sup> (total dust)
United States	TLV-TWA: 10 mg/m <sup>3</sup> TWA: 15 mg/m <sup>3</sup>

  

Limit value type (country of origin)	Substance name	EC-No.	CAS-No.	Monitoring procedures	Occupational exposure limit value	
					Long term mg/m <sup>3</sup>	Short term mg/m <sup>3</sup>
PEL (OSHA)	titanium dioxide	236-675-5	13463-67-7	Photometrical	TWA 15 mg/m <sup>3</sup>	
REL (NIOSH)					Ca	

Sources: OEL – GESTIS database (International limit values for chemical agents)

DNEL/DMEL values:					
Titanium Dioxide					
DNEL/DMEL			Exposure route	Exposure frequency	Remark
Worker		Consumer			
Industry	Professional				
10 mg/m <sup>3</sup>	10 mg/m <sup>3</sup>	10 mg/m <sup>3</sup>	Inhalation	Long-term -local effects	

PNEC values:			
Titanium Dioxide			
PNEC	Value	Assessment factor	Remark/Justifications
aqua (freshwater)	0.127 mg/L	100	Extrapolation method: assessment factor
aqua (marine water)	1 mg/L	10000	Extrapolation method: assessment factor
sediment (freshwater)	1000 mg/kg sediment	100	Extrapolation method: assessment factor
sediment (marine water)	100 mg/kg sediment	1000	Extrapolation method: assessment factor

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soil	100 mg/kg soil	10	Extrapolation method: assessment factor
sewage treatment plant	100 mg/L	10	Extrapolation method: assessment factor
oral	1667 mg/kg food	30	No data are available for toxicity to birds. The PNEC oral is based on the key study on chronic repeated dose oral toxicity for rats, in which rats were fed ad libitum with corn oil with 50000 mg/kg TiO <sub>2</sub> during 103 weeks (National Cancer Institute, 1979). According to the REACH Guidance on information requirements and chemical safety assessment (Table R.10-13), an assessment factor of 30 should be applied to a chronic NOEC for oral toxicity to mammals. This results in a PNEC oral of 1667 mg TiO <sub>2</sub> /kg food.

### 8.2 Exposure controls

#### Occupational exposure controls

<b>Appropriate engineering controls</b>	Use sufficient ventilation to keep employee exposure below recommended limits.
<b>Respiratory protection</b>	Use dust respirator according to the EN149.
<b>Eye/face protection</b>	Use safety dust proof eyewear: safety goggles according to EN166.
<b>Skin protection</b>	Use protective clothing. Hand protection- gloves. Use Neopren or PVC gloves according to EN374 (protection class 3 and higher). Penetration time is more than hour.
<b>General hygiene considerations</b>	Wash hands and face thoroughly with mild soap before eating and drinking. In facilities, where titanium dioxide is handled, eating and food storage are not permitted.

#### Environmental exposure controls

<b>Measures to prevent exposure</b>	In air and wastewater the product doesn't form any toxic compounds in the presence of other substances or factors.
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#### Consumer exposure controls

<b>Measures related to consumer uses of the substance</b>	additional measures are not required.
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## 9 PHYSICAL AND CHEMICAL PROPERTIES.

### 9.1 Information on basic physical and chemical properties

<b>Appearance</b>	white powder
<b>Odour</b>	Odourless
<b>Odour threshold</b>	not applicable
<b>pH</b>	not applicable
<b>Melting point/range (°C)</b>	1843°C for rutile
<b>Initial boiling point/range (°C)</b>	Boiling point of titanium dioxide is ca. 3000 °C.
<b>Flash point (°C)</b>	not applicable
<b>Evaporation rate</b>	not applicable
<b>Flammability</b>	not applicable
<b>Vapour pressure</b>	not applicable
<b>Relative density</b>	rutile=4.26 g/cm <sup>3</sup>
<b>Water solubility (20°C in g/l)</b>	insoluble (below the LOD of 1 µg/L at pH 6, 7 and 8)
<b>Explosive properties</b>	not applicable
<b>Oxidising properties</b>	not applicable

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<b>9.2 Other information</b>
none

**10 STABILITY AND REACTIVITY**

<b>10.1 Reactivity</b>	Not reactive under regular storage and use conditions.
<b>10.2 Chemical stability</b>	Stable under recommended storage and handling conditions. In case of emissions into atmosphere the substance doesn't form toxic compounds.
<b>10.3 Possibility of hazardous reactions</b>	None under normal processing.

**11 TOXICOLOGICAL INFORMATION**

<b>11.1 Information on toxicological effects.</b>	
<b>Toxicokinetics, metabolism and distribution</b>	
<b>Non-human toxicological data</b>	no bioaccumulation potential
<b>Information on toxicological effects</b>	

<b>Acute toxicity</b>				
<b>titanium dioxide</b>				
Exposure	Value	Exposure time period	Species	Method
oral: gavage	LD50: > 5000 mg/kg bw	Acute	rat (CrI:CD(SD)) female	OECD Guideline 425 (Acute Oral Toxicity: Up-and-Down Procedure) EPA OPPTS 870.1100 (Acute Oral Toxicity)
inhalation (whole body)	LC50 (4 h): > 6.82 mg/L	Acute	rat (ChR-CD) male	Hall, G.T. (1979a)

<b>Irritation</b>	<b>Skin</b>	not irritating
	<b>Eye</b>	not irritating
	<b>Respiratory tract</b>	not irritating
<b>Respiratory or skin sensitisation</b>	not sensitising	
<b>Germ cell mutagenicity</b>	Titanium dioxide has been tested in bacterial reverse mutation assays, in vitro gene mutation and clastogenicity tests as well as in vivo. All tests show a negative response, thus titanium dioxide does not require classification for mutagenic properties. The classification criteria acc. to regulation (EC) 1272/2008 as germ cell mutagen are also not met.	
<b>Carcinogenicity</b>	In lifetime inhalation studies rats were exposed for 2 years to respective 10,50 and 250 mg/ m <sup>3</sup> of respirable TiO <sub>2</sub> . Slight lung fibrosis was observed at 50 and 250 mg/ m <sup>3</sup> levels. Microscopic lung tumours were also observed in 13 percent of the rats exposed to 250 mg/ m <sup>3</sup> , an exposed level that caused lung overloading and impairment of rat lungs clearance mechanisms. In further studies these tumours were found to occur only under particle overload conditions in a uniquely sensitive species, the rat, and have little or no relevance for humans. The pulmonary inflammatory response to TiO <sub>2</sub> particles	

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	<p>exposure was also found to be much more severe in rats than in other rodent species.</p> <p>In February 2006, IARC has re-evaluated Titanium dioxide as pertaining to Group 2B: "possibly carcinogenic to humans", based upon inadequate in humans and sufficient evidence in experimental animals for the carcinogenicity of titanium dioxide. IARC evaluation guidelines consider the generation of tumours, in 2 different studies within the same animal species, to be adequate criteria for an assessment of sufficient evidence.</p> <p>The conclusions of several epidemiology studies on more than 20000 TiO<sub>2</sub> industry workers in Europe and the USA did not suggest a carcinogenic effect of TiO<sub>2</sub> dust on the human lung. Mortality from other respiratory diseases, was also not associated with exposure to TiO<sub>2</sub> dust.</p> <p>It is inappropriate to base the evaluation of titanium dioxide as a suspect carcinogen solely on the observation that rats develop lung tumours under condition of lung particle overload, since such tumours induced in rats by inert poorly soluble particles such as titanium dioxide are widely considered as unreliable predictors of hazard to humans. Overall, the epidemiological evidence from well-conducted investigations has not shown that exposure to titanium dioxide is correlated to any detectable carcinogenic potential for humans.</p>
<p><b>Toxicity for reproduction</b></p>	<p>Based on the weight of evidence from the available long-term toxicity/carcinogenicity studies in rodent and the relevant information on the toxicokinetic behaviour in rats it is concluded that TiO<sub>2</sub> does not present a reproductive toxicity hazard.</p>

Repeated dose toxicity				
titanium dioxide				
Exposure	Value	Exposure time period	Species	Method
oral: gavage	NOEL: 24000 mg/kg bw/day	29 consecutive days. (daily)	rat (CrI:CD (SD)IGS BR)	OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents)Mayer T.W.; et al. (2006)
inhalation	NOEC (for carcinogenicity in rats): 50 mg/m <sup>3</sup> air (male/female) NOEC (non-neoplastic changes): 10 mg/m <sup>3</sup> air (male/female)	up to 2 years (6 hours/day, 5 days/week)	rat (Crj: CD(SD)) male/female	combined repeated dose and carcinogenicity (inhalation) (whole body) 10.6 ± 2.1 mg/m <sup>3</sup> (analytical conc.) 50.7 ± 6.65 mg/m <sup>3</sup> (analytical conc.) 250.1 ± 24.7 mg/m <sup>3</sup> (analytical conc.) O'Neal, F.O. (1985) Lee, K.P.; et al. (1985) Warheit D.B.; Frame S.R. (2006)



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### 12 ECOLOGICAL INFORMATION

12.1 Toxicity			
Aquatic toxicity	Effect dose	Exposure time	Species
Acute toxicity to fish	LC50 > 1000 mg/L	96 h	Pimephales promelas
Acute toxicity to aquatic invertebrates	EC50 > 1000 mg/L	72 h	Daphnia magna
Acute toxicity to aglae	EC50 62 mg/L	72 h	Pseudokirchnerella subcapitata (algae)
12.2 Persistence and degradability			
Abiotic Degradation			
Half-time	Method	Remark	
Biodegradation	Degradation/biodegradation testing is not relevant for metals and metal compounds like TiO <sub>2</sub> , which considered as not (bio) degradable.		
12.3 Bioaccumulative potential			
Results from analysis of elemental Ti in plants and corresponding soil or sediment samples indicate to absence of bioaccumulation of Ti in plants. Reliable BSAF factors for plants vary between 0.000 - 0.0008 kg/kg			
12.4 Mobility in soil			
Does not form toxic compounds in air or sewage water, in presence of other substances or TiO <sub>2</sub> factors. Is not transformed in environment.			
12.5 Results of PBT and vPvB assessment			
According to Annex XIII of regulation (EC) 1907/2006 a PBT and vPvB assessment shall not be conducted for inorganic substances.			
12.6 Other adverse effects:			
none			

### 13 DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods	
Appropriate disposal / Product	The product is non-hazardous to be buried in economical or sanitary settlers.
Waste codes / waste designations according to EWC / AVV	No hazardous wastes as per 2000/532/EC.
Appropriate disposal /Packaging	Upon absence of possibility for recycling or utilizing, wastes and tare should be liquidated in accordance with national and local legal regulations.

### 14 TRANSPORT INFORMATION

14.1. UN number	Not applicable
14.2. UN proper shipping name	Not applicable
14.3. Transport hazard class(es)	Not applicable
14.4. Packing group	Not applicable
14.5. Environmental hazards	Not applicable
14.6. Special precautions for user	Not applicable
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

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<b>14.8 Additional information</b>	the product is transportable by all kinds of vehicles in accordance with transport regulations, active for the given kind of transportation. The cargo is not classified as dangerous one in accordance with international carriage regulation. The marking «Prevent from moisturising» is mandatory.
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**15 REGULATORY INFORMATION**

<b>15.1 Safety, health and environmental regulations/legislation specific for the substance</b>	
<b>EU regulation</b>	
Product conformance to the requirements of Resolution by European Council AP (89) 1; Commission Regulation (EC) No. 10/2011; European Packaging Directive 94/62/CEE; Requirements of the Restriction of Hazardous Substances (RoHS) EU 863/2015; Regulation (EC) No 1935/2004	
<b>Other regulations</b>	
Product conformance to the requirements of DIN EN 71, part 3 "Toys safety, migration of separate elements", as of August 2018, category III; Requirements of Administration on sanitary supervision for foods and pharmaceuticals quality (FDA) (21CFR 178.3297); Standard GB 9685-2016 «National Food Safety Standard. Standard for Uses of Additives in Food. Contact Materials and Their Products».	
<b>15.2 Chemical Safety Assessment</b>	
none	

**16 OTHER INFORMATION**

<b>Relevant R- , H-, EUH-phrases</b>	none
<b>Abbreviation</b>	PEL - permissible exposure limit OEL – occupational exposure limit REL – recommended exposure limit DNEL - derived no-effect level PNEC - predicted no effect concentration LD50 – lethal dose LC50 – lethal concentration EC50 - half maximal effective concentration NOAEL - no observed adverse effect level PBT or vPvB - persistent, bioaccumulative and toxic or very persistent very bioaccumulative
<b>Training instructions</b>	The given document is targeted for personnel, dealing with the product carriage and utilization, with the purpose to learn the safety handling rules.
<b>Further information</b>	Persons, subjected to the given document delivery, may undertake the independent estimation of the product appropriateness for their own needs. The user bears responsibility for appropriateness check and information integrity for his specific application sphere. The manufacturer will be grateful for sending the information about the product utilization, to undertake the extended risks evaluation, at the address indicated on page 1 .

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**EXPOSURE SCENARIOS ACCORDING TO CHEMICAL SAFETY REPORT**

Since titanium dioxide is neither classified as dangerous nor does it meet the criteria as a PBT/ vPvB substance, no exposure assessment is required (see REACH Art 14(4) (a) in conjunction with Annex I Section 0.6 (5) of regulation (EC) 1907/2006.)