

**PRETIOX** (pigment grades)**SECTION 1 Identification**

(a) Product identifier used on the label

The product in question, PRETIOX, pigment grades, hereinafter referred to as 'the substance' or 'the product', is chemical substance based on titanium dioxide (TiO<sub>2</sub>).

Product grades in question: **AV01FG, AV01PhG, AV01Z, AV01SF, FS, R200C, R200F, R200H, R200M, R200P, RG18P, RGLP2, RGU, RGX, RGZW**

(b) Other means of identification

Based on available data, none are applicable.

(c) Recommended use of the chemical and restrictions on use

Recommended use: Pigment.

Restrictions on use: Based on available data, none are known.

(d) Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party

Manufacturer and supplier: PRECHEZA a.s

Site: nábř. Dr. Edvarda Beneše 1170/24, Přerov I-Město, 750 02 Přerov, Czech Republic

Phone: +420 581 253 837; GSM: +420 602 752 216; FAX: +420 581 253 830

E-mail: sds@precheza.cz; URL: www.precheza.cz

(e) Emergency phone number

PRECHEZA a.s. +420 581 252 356; GSM +420 602 783 708 (24/7)

POISON CENTER: Na bojišti 1, 128 02 Prague, Czech Republic

Phone +420 224 919 293 or +420 224 915 402 (24/7)

**SECTION 2 Hazard(s) identification**

(a) Classification of the chemical in accordance with paragraph (d) of §1910.1200

The product is not classified.

(b) Signal word, hazard statement(s), symbol(s) and precautionary statement(s) in accordance with paragraph (f) of §1910.1200

Based on available data, none are applicable.

(c) Any hazard(s) not otherwise classified, identified during the classification process

Dustiness.

(d) Unknown acute toxicity

Based on available data, none is known.

**SECTION 3 Composition/information on ingredients**

(a) Chemical name

Titanium dioxide

(b) Common name and synonyms

Pigment White 6 (CI 77 891)

(c) CAS Number and other unique identifiers

13463-67-7

(d) Classified impurities and stabilizing additives contributing to the classification of the substance

Based on available data, none are known.

## **SECTION 4 First-aid measures**

(a) Description of necessary measures according to the different routes of exposure

Generally: Seek medical aid in the case of persistent difficulties.

Inhalation: Move to a fresh air atmosphere.

Skin contact: Wash with water and soap.

Eye contact: Rinse immediately with plenty of water.

Ingestion: No adverse health effects anticipated. Increase intake of liquid to flush from the body.

(b) Most important symptoms/effects, acute and delayed

Based on available data, none are known.

(c) Indication of immediate medical attention and special treatment needed

Based on available data, none are known.

## **SECTION 5 Fire-fighting measures**

(a) Extinguishing media

Suitable extinguishing media: Water fog, foam, dust, CO<sub>2</sub>.

Unsuitable extinguishing media: Based on available data, none are known.

(b) Specific hazards arising from the chemical

Based on available data, none are known.

Hazardous combustion products: Based on available data, none are known.

(c) Special protective equipment and precautions for the fire-fighters

Use appropriate personal protective equipment with regards to the risks, approved by the professional specialist (see SECTION 8).

## **SECTION 6 Accidental release measures**

(a) Personal precautions, protective equipment and emergency procedures

Based on available data, neither special actions nor targeted training shall be taken. Keep unnecessary and unprotected personnel from entering. Spilt wet product is slippery. Use appropriate personal protective equipment (PPE) with regards to the risks, approved by the professional specialist (see SECTION 8).

(b) Methods and material for containment and cleaning up

Sweep up material using any feasible mechanical means. Product discharged in liquid is highly visible even at low concentration. See SECTION 13 for disposal considerations.

## **SECTION 7 Handling and storage**

(a) Precautions for safe handling

Handling: Avoid raising and breathing dust. Observe good industrial hygiene practice for handling chemical substances.

Technical measures: Handling systems and areas should be operated in such a way as to minimize exposure to dust.

Precautions: Avoid raising and breathing dust; local ventilation may be necessary. Take precautionary measures against static discharges.

Advice on usage: Manual handling guidelines should be adhered to when handling sacks.

(b) Conditions for safe storage, including any incompatibilities

Do not store outside exposed to the weather. Take a care to avoid exposure to the moisture.

Store at temperatures not exceeding 50°C.

Packing materials: Use original package/containers.

Incompatible materials: Based on available data, none are known.

## SECTION 8 Exposure controls/personal protection

(a) Exposure limits used or recommended by the manufacturer

Generally: Ensure sufficient ventilation. Reduce inhalation hazards with minimizing the occupational exposure. Comply with the Occupational Exposure Limits found in National Guidance documents. Personal protective equipment, process control as well as health and safety rules shall be applied for reducing exposure hazard.

Component	Exposure Limits	Basis	Entity
Titanium Dioxide	10 mg/m <sup>3</sup>	TLV	ACGIH
	15 mg/m <sup>3</sup> *	PEL	OSHA

\*Total dust

Predicted No Effect Concentration (PNEC):

Type	PNEC	Unit
Aqua (freshwater)	0,127	mg/L
Aqua (marine water)	1	mg/L
Aqua (intermittent releases)	0,61	mg/L
Sediment (freshwater)	1000	mg/kg sediment dw
Sediment (marine water)	100	mg/kg sediment dw
Soil	100	mg/kg soil dw
Sewage treatment plant	100	mg/L
Oral, mammals	1667	mg/kg food

(b) Appropriate engineering controls

Engineering controls and safe systems of work should be used in preference to Personal Protective Equipment (PPE) to minimize the risk of exposure.

(c) Individual protection measures, such as personal protective equipment

Eye/face protection: The use of dustproof goggles or glasses with side protections is recommended if dust concentrations are likely to exceed the occupational exposure limit.

Skin protection: Respect main rules concerning the protection clothes for chemicals handling.

Hand protection: Prolonged exposure should be avoided by wearing suitable impervious protective gloves.

Respiratory protection: A respirator must be used if the dust concentration is likely to exceed the occupational exposure limit. An approved dust respirator is recommended as appropriate depending on dust levels and other workplace factors.

Thermal hazards: Based on available data, none are known.

Hygiene measures: Individuals having sensitive skin may find it beneficial to use a barrier cream or moisturizer when excessive or prolonged contact with the skin is likely.

## SECTION 9 Physical and chemical properties

(a) Appearance (20°C, 1013 hPa): Solid, fine crystalline white powder.

(b) Odor: Based on available data, it is not known.

(c) Odor threshold: Based on available data, it is not known.

(d) pH (at 20°C): Based on available data, it is not applicable.

(e) Melting point/freezing point (°C): >1560.

(f) Initial boiling point and boiling range (°C): ca. 3000.

(g) Flash point: Based on available data, it is not applicable.

(h) Evaporation rate: Based on available data, it is not applicable.

(i) Flammability (solid, gas): Based on available data, it is not known.

(j) Upper/lower flammability or explosive limits: Based on available data, they are not known.

(k) Vapor pressure: Based on available data, it is not applicable.

(l) Vapor density: Based on available data, it is not applicable.

(m) Relative density (at 20°C): ca 4000 kg/m<sup>3</sup>.

- (n) Solubility(ies): in water at 20 °C: <1 µg/L in the range of pH 6 up to 8.
- (o) Partition coefficient n-octanol/water: Based on available data, it is not applicable.
- (p) Auto-ignition temperature: Based on available data, it is not applicable.
- (q) Decomposition temperature: Based on available data, it is not applicable.
- (r) Viscosity: Based on available data, it is not applicable.

## **SECTION 10 Stability and reactivity**

### (a) Reactivity

Based on available data, no dangerous reactions are known in the case of recommended use.

### (b) Chemical stability

Based on available data, the product is stable under normal conditions.

### (c) Possibility of hazardous reactions

Based on available data, none is known.

### (d) Conditions to avoid

Wetting.

### (e) Incompatible materials

Based on available data, none are known.

### (f) Hazardous decomposition products

Based on available data, none are known.

## **SECTION 11 Toxicological information**

### (a) Information on the likely routes of exposure

- aa) Acute toxicity: oral LD<sub>50</sub> >5000 mg/kg bw; inhalation LC<sub>50</sub> >6.82 mg/L air (MMAD=1.55 µm, GSD=1.70 µm). Based on available data, the classification criteria are not met.
- ab) Skin corrosion/irritation: According to test OECD Guideline 404, the substance is not irritant. Based on available data, the classification criteria are not met.
- ac) Serious eye damage/irritation: according to tests OECD Guideline 405, EU Method B.5 and EPA OPPTS 870.2400 the substance does not cause serious eye damage/irritation. Based on available data, the classification criteria are not met.
- ad) Respiratory or skin sensitization: according to tests OECD Guidelines 406 and 429 the substance does not have skin sensitizing properties; the substance does not show respiratory sensitizing properties in animal studies or in exposure related observations in humans. Based on available data, the classification criteria are not met.
- ae) Germ cell mutagenicity: the substance was tested (bacterial reverse mutation assays, in vitro gene mutation, clastogenicity test) with a negative test result. Based on available data, the classification criteria are not met.
- af) Carcinogenicity: Although carcinogenity studies observed formation of lung tumors under condition of lung particle overload, similar pathological changes are not observed in other experimental species. Detailed epidemiological investigations have shown no causative link between titanium dioxide exposure and cancer risk in humans. At workplace exposure concentrations, no lung cancer hazard has been observed. Based on available data, the classification criteria are not met. Nevertheless, the product is indicated by the IARC Monograph as possibly carcinogenic to humans (group 2B) based on insufficient evidence in humans and on sufficient evidence in experimental animals (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 93, 2010).
- ag) Reproductive toxicity: based on the weight of evidence from the available long-term toxicity/carcinogenicity studies in rodents and the relevant information on the toxicokinetic behavior in rats it is concluded that the substance does not present a reproductive toxicity hazard. Based on available data, the classification criteria are not met.
- ah) STOT–single exposure: no reversible or irreversible adverse health effects through oral exposure were observed immediately or delayed after exposure. Based on available data, the classification criteria are not met.

- ai) STOT–repeated exposure: the substance does not show any adverse effects whatsoever in a chronic oral repeated dose toxicity study in rats with a NOAEL of 3500 mg/kg bw/day; the substance is not absorbed to any relevant extent through human skin, thus no toxic effects can be expected via the dermal route of exposure; regarding inhalation route of exposure the following observations have been made in experimental animals and in human epidemiological studies: (i) No systemic toxicity was shown to result from chronic inhalation exposure in rats to high concentrations of pigment grade titanium dioxide, (ii) Particle overload is observed for insoluble particles such as titanium dioxide, whereby the rat is the most sensitive species studied, and species-specific differences are demonstrated in various mechanistic animal studies. It has been demonstrated with reasonable certainty that lung overload conditions are not relevant for human health and, therefore, results based on these data do not justify classification. (iii) It has also been clearly demonstrated through epidemiological studies of titanium dioxide–exposed workers that there is no causal link. Based on available data, the classification criteria are not met.
- aj) Aspiration hazard: Based on available data, the classification criteria are not met.

## SECTION 12 Ecological information

### (a) Ecotoxicity

#### Acute toxicity to aquatic organisms – fish

All reliable acute toxicity tests to fish resulted in LC<sub>50</sub> values ranging from >1 to >10000 mg TiO<sub>2</sub>/L, as observed for 4 different fish species in both fresh and marine water. All these results are taken together in a weight of evidence approach, and it is concluded that TiO<sub>2</sub> is not acute toxic to fish at >1000 mg TiO<sub>2</sub>/L and at >10000 mg TiO<sub>2</sub>/L in freshwater and marine water, respectively.

Results of test of acute toxicity on fish:

Pimephales promelas LC<sub>50</sub> (96 hours): >1000 mg/L, tested according to EPA-540/9-85-006, Acute Toxicity Test for Freshwater Fish

Oncorhynchus mykiss LC<sub>50</sub> (96 hours): >100 mg/L, tested in fresh water, according to OECD Guideline 203 (Fish, Acute Toxicity Test)

Oncorhynchus mykiss LC<sub>50</sub> (14 days): >1 mg/L, tested in fresh water where fish were exposed to a different concentration of tested material and several biochemical endpoints in various organs were measured afterwards.

Danio rerio LC<sub>50</sub> (48 hours): >10 mg/L, tested in fresh water, according to American Society of Testing and Materials (ASTM), 2002

Cyprinodon variegatus LC<sub>50</sub> (96 hours): >10000 mg/L, tested in marine water, according to OECD Guideline 203 (Fish, Acute Toxicity Test) and according to OSPARCOM (2005-11), Protocol for a fish acute toxicity test.

#### Acute toxicity to aquatic organisms – invertebrates

All reliable acute toxicity tests to invertebrates resulted in L(E)C<sub>50</sub> values ranging from >10 to >10000 mg TiO<sub>2</sub>/L, as observed for 4 different invertebrate species in both fresh and marine water. All these results are taken together in a weight of evidence approach, and it is concluded that TiO<sub>2</sub> is not toxic to aquatic invertebrates at >1000 mg TiO<sub>2</sub>/L and at >10000 mg TiO<sub>2</sub>/L in freshwater and marine water, respectively.

Results of test of acute toxicity on invertebrates:

Daphnia magna LC<sub>50</sub> (48 hours): >100 mg/L, tested in freshwater, according to Guideline 202 (Daphnia sp. Acute Immobilization Test)

Daphnia pulex LC<sub>50</sub> (48 hours): >10 mg/L, tested in fresh water, according to American Society for Testing and Materials: Standard guide for conducting acute toxicity tests on test materials with fishes, macro invertebrates and amphibians.

Ceriodaphnia dubia LC<sub>50</sub> (48 hours): >10 mg/L, tested in fresh water, according to American Society for Testing and Materials: Standard guide for conducting acute toxicity tests on test materials with fishes, macro invertebrates and amphibians.

Daphnia magna EC<sub>50</sub> (48 hours): >1000 mg/L, tested in fresh water, according to EPA-660/8-87/011, 1987 and ASTM Standard E729 (1986) and OECD Guideline 202 (Daphnia sp. Acute Immobilization Test) and U.S. Environmental Protection Agency (660/3-75-009), 1975: Methods for Acute Toxicity Tests with Fish, Macro-invertebrates and Amphibians

Daphnia magna LC<sub>50</sub> (48 hours): ≥500 mg/L, tested in fresh water, according to U.S. EPA standard operating procedure 2024

Acartia tonsa LC<sub>50</sub> (48 hours): >10000 mg/L, tested in fresh water, according to ISO 14669 (1999) Water quality-determination of acute lethal toxicity to marine copepods (Copepoda crustacea) and ISO 5667-16 (1998) Water quality sampling-guidance on biotesting of samples

#### Long-term toxicity to aquatic organisms

No reliable chronic toxicity data are available for aquatic invertebrates. As all acute tests show the absence of toxic effects, there is no need for further investigation of effects to aquatic organisms.

#### Toxicity to algae and aquatic plants

The lowest value for growth rate was observed for Pseudokirchneriella subcapitata in fresh water: EC<sub>50</sub> (72 hours) 61 mg TiO<sub>2</sub>/L, test according to OECD Guideline 201 (Alga, Growth Inhibition Test), with a corresponding EC<sub>10</sub> (72 hours) of 12.7 mg TiO<sub>2</sub>/L. Tests with Skeletonema costatum in marine water result resulted in EC<sub>50</sub> of >10000 and a NOEC of 5600 mg TiO<sub>2</sub>/L (growth rate), test according to ISO 10253 (Water quality – Marine Algal Growth Inhibition Test with Skeletonema costatum and Phaeodactylum tricornutum).

#### Toxicity to sediment organisms

EC<sub>50</sub>/LC<sub>50</sub> in marine water sediment: 14989 mg/kg dw (according to test on Corophium volutator according to OSPARCOM guidelines (1995) A sediment Bioassay using an amphipod corophium sp); EC<sub>10</sub>/LC<sub>10</sub> or NOEC in freshwater sediment: 100000 mg/kg sediment dw (according to test on Hyalella azteca according to ASTM E1706).

#### Toxicity to soil macro-organisms

Long-term EC<sub>10</sub>/LC<sub>10</sub> or NOEC for soil arthropods: 1000 mg/kg soil dw, tested on Folsomia candida according to ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants).

#### Toxicity to terrestrial plants

Long-term EC<sub>10</sub>/LC<sub>10</sub> or NOEC for terrestrial plants: 100000 mg/kg soil dw, tested on Hordeum vulgare (Monocotyledonae (monocots) and Lactuca sativa (Dicotyledonae (dicots))), according to ISO 11269-2 protocol.

#### Toxicity to soil micro-organisms

Long-term EC<sub>10</sub>/LC<sub>10</sub> or NOEC for soil micro-organisms: 10000 mg/kg soil dw (tested on species/Inoculum: soil, according to ISO 14238).

#### Toxicity to aquatic micro-organisms in sewage treatment systems

EC<sub>10</sub>/LC<sub>10</sub> or NOEC for aquatic micro-organisms: 1000 mg/L, tested activated sludge of a predominantly domestic sewage, in freshwater, according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test).

#### (b) Persistence and degradability

Based on available data, the product is not considered as being persistent.

#### (c) Bioaccumulative potential

Based on available data, the product is not considered as being bioaccumulative.

#### (d) Mobility in soil

Based on available data, the product is considered as being mobile in soil.

#### (e) Other adverse effects

Based on available data, none are known.

## **SECTION 13 Disposal considerations**

Product residues: Based on available data, the product is not considered as being hazardous waste. Check for possible re-utilization. Pack, label and dispose/recycle according to the applicable national and local regulations. Where large quantities are concerned, consult the supplier.

Uncleansed package: Based on available data, it is not considered to be a hazardous waste. When passed on, the recipient must be warned of any possible hazard that may be caused by residues. If recycling is not possible, dispose it according to the applicable national and local regulations.

## SECTION 14 Transport information

(a) UN number

Based on available data, it is not applicable.

(b) UN proper shipping name

Based on available data, it is not applicable.

(c) Transport hazard class(es)

Based on available data, it is not applicable.

(d) Packing group

Based on available data, it is not applicable.

(e) Environmental hazards

Based on available data, it is not applicable.

(f) Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Based on available data, the product is not considered as carried in bulk according to Annex II of MARPOL and the IBC Code.

(g) Special precautions for user

See SECTION 4 up to SECTION 8.

## SECTION 15 Regulatory information

Safety, health and environmental regulations specific for the product in question

**Based on available data, there is no legal duty and/or other obligation to provide Safety Data Sheet for hereby listed product.**

The manufacturer has performed a chemical safety assessment.

Exposure assessment: Based on the available data, the substance does not meet the PBT and vPvB criteria, so there is no obligation to carry out an exposure assessment.

Risk characterization: Based on the available data, the substance does not meet the PBT and vPvB criteria, so there is no obligation to carry out a risk characterization.

**Based on available data, exposure scenarios are not relevant for hereby listed product.**

The State of California through The Office of Environmental Health Hazard Assessment (OEHHA) within the California Environmental Protection Agency added titanium dioxide (airborne, unbound particles of respirable size) to the list of chemicals known to the State of California to cause cancer for purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) using the Labor Code listing mechanism. The listing is based on the International Agency for Research on Cancer's (IARC), Monograph No. 93, published in 2010, that changed the classification of TiO<sub>2</sub> to possibly carcinogenic to humans (2B). The listing does not cover titanium dioxide when it remains bound within a product matrix. The listing of titanium dioxide (airborne, unbound particles of respirable size) is effective September 2, 2011. This does not require warnings on products containing titanium dioxide, such as on paint / plastics / paper containing titanium dioxide, etc., however, titanium dioxide-containing products sold in the State of California that meet the listing criterion (airborne, unbound particles of respirable size) require the warning under Proposition 65 beginning no later than September 1, 2012. Employee communication for those working with dry titanium dioxide is also required as of the same date.

## SECTION 16 Other information

### **Revision and update of this Safety Data Sheet**

*The manufacturer revises this Safety Data Sheet after every 12 months after the date of validity or if new information with influence on risk assessment is available or when permitting/restriction is given. If it conforms, it stays in use, among other on internet pages of manufacturer [www.preceza.cz](http://www.preceza.cz). If it does not conform, it is updated and issued with increased number of editions.*

### **Changes against the last edition of this Safety Data Sheet**

*Repeals and replaces Safety Data Sheet PRETIOX (grades not containing TMP); edition US1; valid since 21 August 2020*

**Key or legend to abbreviations and acronyms used in the safety data sheet:**

DNEL Derived No Effect Level, the level of exposure to a substance above which humans should not be exposed  
PNEC Predicted No Effect Concentration, the limit at which below no adverse effects of exposure in an ecosystem are measured

**Key literature/information references and sources of data:**

Appendix D of 29 CFR 1910.1200  
UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS)  
Documentation of European Chemical Agency (ECHA); <https://echa.europa.eu>  
Safety Data Sheets of raw material suppliers  
Safety data sheets of analogous products  
Database PhysProp; <http://esc.syrres.com/interkow>  
Ecotoxicological database; <http://www.piskac.cz/ETD>  
Database ICSC (WHO/IPCS/ILO); <http://www.cdc.gov/niosh/ipcs>  
Chemical Safety Report, Titanium Dioxide, Tioxide Europe Limited, (2010)

**A list of relevant hazard statements and/or precautionary statements**

N/A

**Advice on training appropriate for workers to ensure protection of human health and the environment**

Keep all rules valid for handling chemical substances and mixtures.

**Disclaimer**

Hereby mentioned product is intended for industrial and related applications only (e.g. research and development) by aware and capable staff.

Information included in this document is given in good faith with accentuation that:

- ★ not applicable legal and/or other requirements and/or qualitative attributes of the product(s) are stated as "not relevant". "not applicable" or "N/A" in this Safety Data Sheet;
- ★ not known legal and/or other requirements and/or qualitative attributes of the product(s) are stated as "not known" in this Safety Data Sheet;
- ★ all the hereby given data reflects the best recent stage of knowledge relevant to safety and hygienic requirements;
- ★ all the hereby given data cannot be used as the warranty of the product(s) quality and cannot be used for complaints;
- ★ former application tests are necessary before any use of the hereby mentioned product(s);
- ★ all relevant and known regulations and rules for handling with chemical substances and mixtures have to be kept in case of use, handling and/or transport the hereby mentioned product(s);
- ★ the exploitation of hereby mentioned information is not controlled by the producer; the producer does not accept responsibility for any injury and/or damage when/where hereby mentioned product(s) is used by incompetent manner and/or in applications other than recommended and/or identified;
- ★ the user of the hereby mentioned product(s) is responsible to respect all applicable industrial and other rights related to the hereby mentioned product(s).

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