PRECHEZA **SAFETY DATA SHEET**

According to Commission Regulation (EU) № 2020/878

PRETIOX *(pigment grades)*

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier
The product in question sold under the trade mark/name PRETIOX, hereinafter referred to as 'the substance' or 'the product', is a chemical substance based on titanium dioxide (TiO_2).
Product grades in question: **AV01FG, AV01PhG, AV01Z, AV01SF, FS, R200C, R200F, R200H, R200M, R200P, RG18P, RGLP2, RGU, RGX, RGZW**

1.2. Relevant identified uses of the substance or mixture and uses advised against
Identified uses: Pigment.
Uses advised against: Based on available data, none are stated.

1.3. Details of the supplier of the safety data sheet
Producer and supplier: PRECHEZA a.s
Site: nábř. Dr. Edvarda Beneše 1170/24, Přerov I-Město, 750 02 Přerov, Czech Republic
Phone: +420 581 706 837; GSM: +420 602 752 216; FAX: +420 581 706 830
E-mail: sds@precheza.cz; URL: www.precheza.cz

1.4. Emergency telephone 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

2.1. Classification of the substance or mixture

2.1.1 Classification according to the Regulation (EC) № 1272/2008 (CLP)
The product is not classified.

2.1.2 Additional information
Commission Delegated Regulation (EU) № 2020/217 classified titanium dioxide (TiO_2) in powder form containing 1 % or more particles with an aerodynamic diameter ≤10 μm as a carcinogen category 2 by inhalation. Particle analysis confirms that there is no requirement to classify the above mentioned product PRETIOX (pigment grades).

2.2. Label elements
Signal word: None.
Hazard pictogram: None.
Hazard statement: None.
Precautionary statements: None

2.3. Other hazards
Dangerous respirable dust may be generated when using a powdered substance.
Based on available data, the substance does not meet the criteria for being persistent, bioaccumulative and toxic or very persistent and very bioaccumulative and does not have endocrine disrupting properties.

SECTION 3: Composition/information on ingredients

3.1. Substances
Main constituent: Titanium dioxide, CAS № 13463-67-7, EINECS № 236-675-5, Index № 022-006-002, REACH registration № 01-2119489379-17-0013

3.2. Mixtures
Not applicable.

SECTION 4: First-aid measures

4.1. Description of first aid measures
General: Seek medical aid in the case of persisting difficulties.
When breathed in: Move the affected person to fresh air and keep him at rest in a position comfortable for breathing, do not let him walk. Preserve him against cooling, loosen tight clothing, collar, tie or belt. Rinse his mouth and nose with water.
If on skin/hair: Wash the affected area with water and soap. Take off all contaminated clothing and wash it before reuse.
If in eyes: Rinse affected eye with running water. Open the eyelids and remove contact lenses if the affected person has them. Rinse for at least 10 minutes from the inner corner of the eye to the outer.
When swallowed: No adverse health effects are anticipated. Do not induce vomiting. Rinse the affected person's mouth with water and give him to drink 2 to 3 dL of water. Do not give anything by mouth if the affected person is unconscious.

4.2. Most important symptoms and effects, both acute and delayed
Based on available data, none are known.

4.3. Indication of any immediate medical attention and special treatment needed
Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water fog, foam, dust, CO_2. The product is not combustible.
Unsuitable extinguishing media: Based on available data, none are known.

5.2. Special hazards arising from the substance or mixture
Based on available data, none are known.
Hazardous combustion products: Based on available data, none are known.

5.3. Advice for fire-fighters
Use appropriate personal protective equipment (see SECTION 8).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Based on available data, neither special actions nor targeted training shall be taken. Use appropriate personal protective equipment (see SECTION 8). Keep unnecessary personnel from entering. Spilt wet product is slippery.

6.2. Environmental precautions
Close the place of leaking and prevent leaking into the environment by an appropriate absorption material (sand, broken stone). Inform relevant authorities if a contamination of rivers, lakes or water sources occurs.

6.3. Methods and material for containment and cleaning up
See SECTION 13 for disposal considerations.

6.4. Reference to other sections
See SECTION 1 for emergency phone number. See SECTION 8 for exposure controls/personal protection. See SECTION 13 for disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Warning: Based on available data, none are known.
Handling: Keep hygienic rules for handling chemical substances and mixtures. Do not eat, drink, smoke or chew in the workplace. Take off contaminated clothing in an appropriate manner and wash it before reuse. Wash hands after work. Take off contaminated clothing and personal protective equipment before entering the dining area.
Recommendations for users: Service personnel must be qualified through education and training.

Technical measures: Keep production and processing lines closed to reduce possible leaks. Use a dust reduction device when filling transport packaging. Use special collection and cleaned tubs/tanks when handling large volumes of the substance. If the product is packaged in bags, apply local operational safety regulations for bag handling.

7.2. Conditions for safe storage, including any incompatibilities
Do not store outside exposed to the weather. Avoid exposure to the moisture.
Recommended packing materials: Use original package/containers.
Incompatible materials: Based on available data, none are known.

7.3. Specific end use(s)
Based on available data, none are known.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Generally: Ensure sufficient ventilation. Reduce inhalation hazards. Keep the Occupational Exposure Limits found in National Guidance documents. Personal protective equipment, process control as well as health and safety rules shall be applied.

Derived No Effect Level (DNEL):

Type	*Exposure route*	*DNEL*	*Unit*
Chronic, local	Inhalation	10	mg/m^3

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

8.2. Exposure controls

8.2.1 Appropriate engineering controls
An assessment of the effectiveness of ventilation or other measures and/or the use of personal respiratory protective equipment may be required in accordance with local regulations.

8.2.2 Individual protection measures, such as personal protective equipment
General: Personal protective equipment must be appropriate to the nature of the work to be performed, taking the risks into account and must be approved in advance by a professional.
Eye/face protection: Use the dustproof goggles or glasses with side protections.
Skin protection: Wear protective clothes and impervious protective gloves.
Respiratory protection: A respirator or mask with filter B/P2 must be used if the dust concentration is likely to exceed the occupational exposure limit.
Thermal hazards: Based on available data, none are known.
Hygiene measures: Individuals having sensitive skin may use a barrier cream or moisturizer during work.

8.2.3 Environmental exposure controls
Do not allow the product to contaminate the environment. Monitor emissions from ventilation and process equipment to ensure compliance with environmental protection requirements. In some cases, it may be necessary to use scrubbers, filters or other technical modifications to the equipment to reduce emissions to acceptable limits.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
(a) Physical state (20 °C, 1013 hPa): Solid, fine crystalline powder
(b) Colour: White

(c) Odour: Based on available data, it is not known
(d) Melting point/freezing point (°C): >1560
(e) Initial boiling point and boiling range (°C): ca. 3000
(f) Flammability (solid, gas): Based on available data, it is not known
(g) Lower and upper explosion limit: Based on available data, it is not applicable
(h) Flash point: Based on available data, it is not applicable
(i) Auto-ignition temperature: Based on available data, it is not applicable
(j) Decomposition temperature: Based on available data, it is not applicable
(k) pH (at 20 °C): Based on available data, it is not applicable
(l) Kinematic viscosity: Based on available data, it is not applicable
(m) Solubility: in water, <1 µg/L in the range of pH 6 to 8
(n) Partition coefficient n-octanol/water: Based on available data, it is not applicable
(o) Vapour pressure: Based on available data, it is not applicable
(p) Density and/or relative density (at 20 °C): 3900 až 4260 kg/m^3; bulk 500 až 1040 kg/m^3; tamped 780 až 1200 kg/m^3
(q) Relative vapour density: Based on available data, it is not applicable
(r) Particle characteristic: The mean size of the primary particles is greater than 100 nm (found by TEM/SEM)

9.2. Other information
(s) Evaporation rate: Based on available data, it is not applicable
(t) Explosive properties: Based on available data, none are known
(u) Oxidising properties: Based on available data, none are known

SECTION 10: Stability and reactivity

10.1. Reactivity
Based on available data, no reactivity hazards of the substance are known in the case of recommended storage and use.

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

10.3. Possibility of hazardous reactions
Based on available data, none are known.

10.4. Conditions to avoid
Wetting.

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

10.6. Hazardous decomposition products
Based on available data, none are known.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

(a) Acute toxicity: oral LD_{50} >5000 mg/kg bw, inhalation LC_{50} >6.82 mg/L air (MMAD=1.55 µm, GSD=1.70 µm). Based on available data, the classification criteria are not met.
(b) Skin corrosion/irritation: According to test OECD Guideline 404, the substance is not irritant. Based on available data, the classification criteria are not met.
(c) 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.
(d) 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.
(e) 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.

(f) Carcinogenicity: Commission Delegated Regulation (EU) № 2020/217 classified titanium dioxide (TiO_2) in powder form containing 1 % or more particles with an aerodynamic diameter ≤10 μm as a carcinogen category 2 by inhalation. The substance is indicated by the IARC Monograph as possibly carcinogenic to humans (group 2B). However, detailed epidemiological studies have not shown an association between substance exposure and cancer risk.
(g) 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.
(h) 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.
(i) 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.
(j) Aspiration hazard: Based on available data, the classification criteria are not met.

11.2. Information on other hazards
Based on available data, none are known.

SECTION 12: Ecological information

12.1. Toxicity

Acute toxicity to aquatic organisms – fish
All reliable acute toxicity tests to fish resulted in LC_{50} values ranging from >1 to >10000 mg TiO_2/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_2 is not acute toxic to fish at >1000 mg TiO_2/L and at >10000 mg TiO_2/L in fresh water and marine water, respectively.
Results of test of acute toxicity on fish:
Pimephales promelas LC_{50} (96 hours): >1000 mg/L, tested according to EPA-540/9-85-006, Acute Toxicity Test for Freshwater Fish
Oncorhynchus mykiss LC_{50} (96 hours): >100 mg/L, tested in fresh water, according to OECD Guideline 203 (Fish, Acute Toxicity Test)
Oncorhynchus mykiss LC_{50} (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_{50} (48 hours): >10 mg/L, tested in fresh water, according to American Society of Testing and Materials (ASTM), 2002
Cyprinodon variegatus LC_{50} (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_{50} values ranging from >10 to >10000 mg TiO_2/L, as observed for 4 different invertebrate species in both fresh water and marine water. All these results are taken together in a weight of evidence approach, and it is concluded that TiO_2 is not toxic to aquatic invertebrates at >1000 mg TiO_2/L and at >10000 mg TiO_2/L in fresh water and marine water, respectively.

Results of test of acute toxicity on invertebrates:
Daphnia magna LC_{50} (48 hours): >100 mg/L, tested in fresh water, according to Guideline 202 (Daphnia sp. Acute Immobilization Test)
Daphnia pulex LC_{50} (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_{50} (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_{50} (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_{50} (48 hours): ≥500 mg/L, tested in freshwater, according to U.S. EPA standard operating procedure 2024
Acartia tonsa LC_{50} (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_{50} (72 hours) 61 mg TiO_2/L, test according to OECD Guideline 201 (Alga, Growth Inhibition Test), with a corresponding EC_{10} (72 hours) of 12.7 mg TiO_2/l. Tests with Skeletonema costatum in marine water result resulted in EC_{50} of >10000 and a NOEC of 5600 mg TiO_2/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_{50}/LC_{50} 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_{10}/LC_{10} 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_{10}/LC_{10} 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_{10}/LC_{10} 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_{10}/LC_{10} 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_{10}/LC_{10} 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).

12.2. Persistence and degradability
Based on available data, the substance is not considered as being persistent or degradable.

12.3. Bioaccumulative potential
Based on available data, the substance is not considered as being bioaccumulative.
12.4. Mobility in soil
Based on available data, the substance is not considered as being mobile in soil.

12.5. Results of PBT and vPvB assessment
Based on available data, the substance is not considered as being PBT or vPvB.

12.6. Endocrine disrupting properties
Based on available data, none are known.

12.6. Other adverse effects
Based on available data, none are known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Product residues: Check the possibilities for re-utilization. Pack, label and dispose/recycle according to the applicable national and local regulations. Where large quantities are concerned, consult the supplier.
Contaminated packaging: Based on available data, they are not regarded as 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 according to the applicable national and local regulations.
Dangerous wastes: Based on available data, the product is not regarded as hazardous waste. EWL code 06 11 99.

SECTION 14: Transport information

14.1. UN number ot ID Number
Based on available data, it is not applicable.

14.2. UN proper shipping name
Based on available data, it is not applicable.

14.3. Transport hazard class(es)
Based on available data, it is not applicable.

14.4. Packing group
Based on available data, it is not applicable.

14.5. Environmental hazards
Based on available data, none are known.

14.6. Special precautions for user
See SECTIONS 4 up to 8.

14.7. Maritime transport in bulk according to IMO instruments
Based on available data, cargoes are not intended to be carried in bulk according to IMO instruments.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
Based on the available data information, the EU safety, health and environmental provisions applicable to the hereby mentioned substance are not known.
Based on available data, there is no legal and/or other obligation to provide safety data sheet for hereby mentioned product.

15.2 Chemical safety assessment
The manufacturer has performed a chemical safety assessment.
Exposure Assessment: Based on available data, the product is not considered as being hazardous and it does not meet the PBT and vPvB criteria, ie. there is no obligation to perform an exposure assessment.
Risk Characterisation: Based on available data, the product is not considered as being hazardous and it does not fulfil the PBT and vPvB criteria, ie. there is no obligation to perform a risk characterisation.
Based on available data, exposure scenarios are not relevant for the hereby mentioned product.

SECTION 16: Other information

Revision and update of this Safety Data Sheet
The manufacturer revises this Safety Data Sheet every 12 months after the date of validity or if new information with influence on risk assessment is available or permitting/restriction is given. If it conforms, it stays in use, among other on internet pages of manufacturer www.precheza.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 Safety Data Sheet PRETIOX, TMP and nonTMP grades, edition EN1; valid since 01 July 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 references and sources of data
Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
Comission Regulation (EC) 2020/878 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
Comission Delegated Regulation (EU) 2020/217, amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation
UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS)
Safety Data Sheets of raw material suppliers
Safety data sheets of analogous products
Database PhysProp; http://esc.syrres.com/interkow
Ecotoxikological database; http://www.piskac.cz/ETD
Database ICSC (WHO/IPCS/ILO); http://www.cdc.gov/niosh/ipcs
Chemical Safety Report, Titanium Dioxide

The methods of evaluating information referred to in Article 9 of Regulation (EC) No 1272/2008 used for the purpose of classification
Not applicable

A list of relevant hazard statements and/or precautionary statements
Not applicable

Advice on any training appropriate for workers to ensure protection of human health and the environment
Keep all rules applicable on handling chemical substances and mixtures.

Disclaimer
Hereby mentioned product is intended for industrial and related applications only (eg. 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" in this Safety Data Sheet;*
- *not known applicable 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).*

- - - End of the document - - -