

According to OSHA as detailed in Appendix D of 29 CFR 1910.1200

# **PRETIOX** (product groups A, R, F)

This Safety Data Sheet refers to all grades of titanium dioxide PRETIOX within the product groups of PRETIOX A, PRETIOX R and PRETIOX F originated from PRECHEZA a.s., manufactured and supplied in the solid state.

#### **SECTION 1: Identification**

- (a) Product identifier used on the label PRETIOX
- (b) Other means of identification None are applicable.
- (c) Recommended use of the chemical and restrictions on use

Recommended use: manufacturing of paints, plastics, fibers, paper, leather products, rubber products, enamels, ceramic products, food and cosmetic products as well as in other industrial segments.

Restrictions on use: 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: +420 581 706 837; GSM: +420 602 752 216; FAX: +420 581 706 830

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 No classification.
- (b) Signal word, hazard statement(s), symbol(s) and precautionary statement(s) in accordance with paragraph (f) of §1910.1200 Not applicable.
- (c) Any hazard(s) not otherwise classified, identified during the classification process None are known.
- (d) Unknown acute toxicity Not applicable.

### **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 Not applicable.

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

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

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.

Generally: Consult a doctor in case of persistent difficulties.

(b) Most important symptoms/effects, acute and delayed None are known.

(c) Indication of immediate medical attention and special treatment needed None are known.

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

(a) Extinguishing media

Suitable: Use any media appropriate to local conditions and surrounding environment.

Unsuitable: None are known.

(b) Specific hazards arising from the chemical

None are known.

(c) Special protective equipment and precautions for the fire-fighters Use appropriate personal protective equipment (see SECTION 8 c).

### **SECTION 6: Accidental release measures**

(a) Personal precautions, protective equipment and emergency procedures Avoid generation of dust. Ensure adequate ventilation. Use appropriate personal protective equipment (see SECTION 8 c).

(b) Methods and material for containment and cleaning up

Use any feasible mechanical means (e.g. vacuum, sweeping), avoid dusting. It can cause slippery conditions if wet. Discharged in liquid, it is highly visible at low concentration already.

### **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: Avoid handling dust. Handling systems and areas should be operated in such a way as to minimize exposure to dust.

Precautions: Local exhaust ventilation may be necessary. Handle minimizing dust. 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

The product should not be stored outside exposed to the weather. Care should be taken to avoid exposure to moisture.

Packing materials: Paper, plastic.

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

### \*Total dust

DNEL 10 mg/m³ (long-term, inhalation route, generally for nuisance dust, i.e. no specific

hazard from the substance)

PNEC aqua (freshwater): 0.127 mg/L PNEC aqua (marine water): 1 mg/L

PNEC aqua (intermittent releases): 0.61 mg/L

PNEC sediment (freshwater): 1000 mg/kg sediment dw PNEC sediment (marine water): 100 mg/kg sediment dw

PNEC soil: 100 mg/kg soil dw

PNEC (sewage treatment plant): 100 mg/L PNEC (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

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.

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.

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

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: Odorless.
- (c) Odor threshold: Not applicable.
- (d) pH (at 20°C): Not applicable.
- (e) Melting point/freezing point (°C): > 1560
- (f) Initial boiling point and boiling range (°C): ca. 3000
- (g) Flash point: Not applicable.
- (h) Evaporation rate: Not applicable.
- (i) Flammability (solid, gas): Nonflammable.
- (j) Upper/lower flammability or explosive limits: Not applicable.
- (k) Vapor pressure: Not applicable.
- (I) Vapor density: Not applicable.
- (m) Relative density (at 20°C):  $3900 \div 4260 \text{ kg/m}^3$ ; bulk density  $500 \div 1040 \text{ kg/m}^3$ ; bulk density tamped  $780 \div 1200 \text{ kg/m}^3$
- (n) Solubility(ies):  $< 1 \mu g/L$  in the range of pH 6 ÷ 8 (in water)
- (o) Partition coefficient n-octanol/water: Not applicable.
- (p) Auto-ignition temperature: Not applicable.
- (q) Decomposition temperature: Not known.
- (r) Viscosity: Not applicable.

# **SECTION 10: Stability and reactivity**

(a) Reactivity

No dangerous reactions are known in case of recommended use.

(b) Chemical stability

The product is stable under normal conditions.

- (c) Possibility of hazardous reactions None are known.
- (d) Conditions to avoid Wetting.
- (e) Incompatible materials None are known.
- (f) Hazardous decomposition products None are known.

# **SECTION 11: Toxicological information**

- (a) Information on the likely routes of exposure
- aa) Acute toxicity:
  - oral  $LD_{50} > 5000 \text{ mg/kg bw}$ ;
  - 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.
- 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.

  Safety Data Sheet PRETIOX A, R, F

  Edition 15 (US), valid since 01 May 2015 until cancelled Amends Safety Data Sheet PRETIOX A, R, F, S; edition 14 (EN); valid since 01 March 2014

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  Revision: After every 12 month after the date of validity, see SECTION 16 Amends Safety Data Sheet PRETIOX A, R, F, S; edition 14 (EN); valid since 01 March 2014

# **SECTION 12: Ecological information**

# (a) Ecotoxicity

Acute toxicity to aquatic organisms - fish

All reliable acute toxicity tests to fish resulted in  $LC_{50}$  values ranging from >1 to >10000 mg  $TiO_2/I$ , as observed for 4 different fish species in both freshwater and salt 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  $TiO_2/I$  and at >10000 mg  $TiO_2/I$  in freshwater and marine water, respectively.

Results of test of acute toxicity on fish:

Pimephales promelas  $LC_{50}$  (96 hours): > 1 000 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 freshwater, according to OECD Guideline 203 (Fish, Acute Toxicity Test)

Oncorhynchus mykiss  $LC_{50}$  (14 days): > 1 mg/L, tested in freshwater 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 freshwater, according to American Society of Testing and Materials (ASTM), 2002

Cyprinodon variegatus  $LC_{50}$  (96 hours): > 10 000 mg/L, tested in saltwater, 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>/I, as observed for 4 different invertebrate species in both freshwater and salt 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>/I and at >10000 mg TiO<sub>2</sub>/I in freshwater and marine water, respectively.

Results of test of acute toxicity on invertebrates:

Daphnia magna  $LC_{50}$  (48 hours): > 100 mg/L, tested in freshwater, according to Guideline 202 (Daphnia sp. Acute Immobilization Test)

Daphnia pulex  $LC_{50}$  (48 hours): > 10 mg/L, tested in freshwater, 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 freshwater, 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 freshwater, 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 freshwater, according to ISO 14669 (1999) Water quality-determination of acute lethal toxicity to marine copepods (Copepoda crustacea) a 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  $TiO_2/I$ , test according to OECD Guideline 201 (Alga, Growth Inhibition Test), with a corresponding  $EC_{10}$  (72 hours) of 12.7 mg  $TiO_2/I$ . Tests with Skeletonema costatum in marine water result resulted in  $EC_{50}$  of >10000 and a NOEC of 5600 mg  $TiO_2/I$  (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).

(b) Persistence and degradability

Based on available data, it is non-persistent and non-degradable. See SECTION 9 for decomposition and solubility.

(c) Bioaccumulative potential

Aquatic bioaccumulation: Ti concentrations in various fish tissues stayed constant over the concentration range of  $TiO_2$  in water tested (0÷1 mg  $TiO_2/L$ ), resulting in decreasing BCF with increasing  $TiO_2$  concentrations. The substance is not considered as bioaccumulative. Terrestrial bioaccumulation: No reliable results are available for the bioaccumulation of  $TiO_2$  in terrestrial organisms. Read-across approach pointed the absence of bioaccumulation of Ti in plants due to equilibrium conditions for Ti in the environment.

(d) Mobility in soil

Based on available data, the substance is not mobile in soil.

(e) Other adverse effects

Based on available data, it is not PBT and/or vPvB and none other adverse effects are known, like effect on environmental fate (exposure), photochemical ozone creation potential, ozone depletion potential, endocrine disrupting potential and/or global warming potential.

### **SECTION 13: Disposal considerations**

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.

Uncleansed packages: Based on knowledge, 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 knowledge, the substance is not regarded as hazardous waste.

# **SECTION 14: Transport information**

(a) UN number Not applicable.

(b) UN proper shipping name Not applicable.

(c) Transport hazard class(es) Not applicable.

- (d) Packing group Not applicable.
- (e) Environmental hazards Not applicable.
- (f) Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No limitations are known.
- (g) Special precautions for user See SECTIONS 4 up to 8.

# **SECTION 15: Regulatory information**

Safety, health and environmental regulations specific for the product in question There is no legal duty to provide Safety Data Sheet for the substance.

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  $\text{TiO}_2$  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**

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.

Revision of this Safety Data Sheet

This Safety data sheet is revised by the manufacturer after every 12 months after the date of validity and/or if new information with influence on risk assessment is available and/or permitting/restriction 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 again with increased number of edition.

Changes against the last edition of this Safety Data Sheet Application of Appendix D of 29 CFR 1910.1200

Key literature/information references and sources:
Appendix D of 29 CFR 1910.1200
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, Tioxide Europe Limited, (2010)

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" 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);
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