

according to the Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as well as the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 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

PRETIOX UVS30

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

1.1 Product identifier

Titanium dioxide PRETIOX UVS30, hereinafter referred to as 'the product' or 'the substance' is a chemical substance based on titanium dioxide (TiO_2); CAS 13463-67-7; EINECS 236-675-5; Registration number 01-2119489379-17-0013.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: Raw materials for cosmetics.

Uses advised against: None.

1.3. Details of the supplier of the safety data sheet

Producer and supplier: PRECHEZA a.s, Reg. No. CZ26872307

Site nábrř. Dr. Edvarda Beneře 1170/24, Přerov I-Město, 750 02 Přerov

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 bojiřti 1, 128 02 Prague, Phone +420 224 919 293 or +420 224 915 402 (24/7)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under Regulation (ES) 1272/2008

No classification.

Classification under Directive 67/548/EHS

No classification.

2.2. Label elements

Label elements according to the Regulation (ES) 1272/2008

Signal word: None.

Hazard pictogram: None.

Hazard statement: None.

Precautionary statements: None

Label elements according to the Directive 67/548/EHS

Warning symbol: None.

Risk phrase: None.

Safety phrases: None.

Remark: The product is not a subject to the harmonized classification.

2.3. Other hazards

Not applicable.

SECTION 3: Composition/information on ingredients

3.1. Substances

Main constituent

Name: Titanium dioxide
CAS: 13463-67-7
EINECS: 236-675-5

Impurities

No impurities are relevant to the classification and labelling of the substance.

3.2. Mixtures

Not applicable.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: Move to a fresh air atmosphere. In case of persistent difficulties, consult a doctor.

Skin contact: Wash with soap and water.

Eye contact: Rinse immediately with plenty of water. In case of persistent difficulties, consult a doctor.

Ingestion: No adverse health effects anticipated by this route, however, in the event of ingestion, increase intake of liquid in order to flush from the body. In case of persistent difficulties, consult a doctor.

4.2. Most important symptoms and effects, both acute and delayed

Not known.

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

Not known.

SECTION 5: Fire fighting measures

5.1. Extinguishing media

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

Unsuitable extinguishing media: None stated.

5.2. Special hazards arising from the substance or mixture

None. The product is inert, non flammable and non combustible.

5.3. Advice for fire-fighters

Use usual personal protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid generation of dust. Ensure adequate ventilation. Wear personal protective equipment.

6.2. Environmental precautions

Powder materials: Seal the place of leaking and prevent it leaking into the environment, a sewer system and natural waterways. Inform relevant authorities if a contamination of rivers, lakes or water sources occurs.

6.3. Methods and material for containment and cleaning up

Use any feasible mechanical means (e.g. vacuum, sweeping) but avoid dusting during clean-up. The product can cause slippery conditions if wet. Even at low concentration, the product renders the discharge in liquid effluent highly visible.

6.4. Reference to other sections

Emergency telephone number: see section 1. Exposure controls/personal protection: see section 8. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1. 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 minimise exposure to dust.

Precautions: Local exhaust ventilation may be necessary. Handle minimising dust. Take precautionary measures against static discharges.

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

7.2. Conditions for safe storage, including any incompatibilities

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

Packing materials: Paper, plastic.

Incompatible materials: None.

7.3. Specific end use(s)

None addressed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

General: Ensure sufficient ventilation. Reduce inhalation hazards in minimising the occupational exposure. Comply with the Occupational Exposure Limits found in National Guidance documents. For reducing exposure hazards personal protective equipment, process control as well as health and safety rules should be applied.

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

8.2. Exposure controls

8.2.1 Appropriate engineering controls

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

8.2.2 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.

8.2.3 Environmental exposure controls

Do not allow material to contaminate ground water system.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- (a) Appearance (20°C, 1013 hPa): Solid, fine crystalline white powder.
- (b) Odour: Odourless.
- (c) Odour threshold: Not applicable (the substance is odourless).
- (d) pH (at 20°C): Not applicable for powder grades (solid)
- (e) Melting point/freezing point (°C): > 1560
- (f) Initial boiling point and boiling range (°C): ca. 3000
- (g) Flash point: Not applicable (solid with a melting point > 1560 °C)
- (h) Evaporation rate: Not applicable (solid with a melting point > 1560 °C)
- (i) Flammability (solid, gas): Non flammable (inorganic oxide in which the cation is in highest possible oxidation state and which is incapable to further react with oxygen; does not contain chemical groups that might lead to spontaneous ignition after coming in contact with air or that might react with water developing dangerous amounts of flammable gases)
- (j) Upper/lower flammability or explosive limits: Not applicable (the substance is non flammable and non explosive)
- (k) Vapour pressure: Not applicable (solid with a melting point > 1560 °C)
- (l) Vapour density: Not applicable (solid)
- (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 in water: < 1 µg/l in the range of pH 6 to 8
- (o) Partition coefficient n-octanol/water: Not applicable (inorganic substance)
- (p) Auto-ignition temperature: Not applicable (the substance is inorganic oxide in which the cation is in its highest possible oxidation state and which is incapable of further reaction with oxygen; the substance is not intrinsically ignitable)
- (q) Decomposition temperature: Not applicable, thermodynamically stable form of the product.
- (r) Viscosity: Not applicable (solid)
- (s) Explosive properties: Non explosive (the substance contains titanium in its highest oxidation state)
- (t) Oxidising properties: Not applicable (the substance does not contain a surplus of oxygen or any structural groups with a tendency to react exothermally with a combustible material)

9.2 Other information

- u) Particle size, particle size distribution: Nanomaterial, $d_{50} 90 \div 110 \text{ nm}$, $\sigma 35 \div 45 \text{ nm}$
- v) Shape: oval
- w) Porosity: not known
- x) Aggregate/Agglomerate stage: not known
- y) Morphology: oval shape
- z) Surface area (BET, m^2/g): $40 \div 60 \text{ m}^2/\text{g}$
- aa) Surface charge: not known
- ab) Zeta potential: +30/-30
- ac) Crystalline phase: rutile

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reaction known in case of identified uses.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

Wetting.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

a) Acute toxicity:

- oral – $LD_{50} > 5000$ mg/kg bw;
- inhalation – $LC_{50} > 6.82$ mg/l air (MMAD=1.55 μ m, GSD=1.70 μ m)

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 sensitisation: according to tests OECD Guidelines 406 and 429 the substance does not have skin sensitising properties; the substance does not show respiratory sensitising 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: Although carcinogenity studies observed formation of lung tumours 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).

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 behaviour 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.

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 $>10\,000$ mg TiO_2/l , 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/l and at $>10\,000$ mg TiO_2/l 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 $L(E)C_{50}$ values ranging from >10 to $>10\,000$ mg TiO_2/l , 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_2 is not toxic to aquatic invertebrates at $>1\,000$ mg TiO_2/l and at $>10\,000$ mg TiO_2/l 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 Immobilisation 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): $> 1\,000$ 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 Immobilisation 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): $> 10\,000$ 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/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 $>10\,000$ and a NOEC of 5 600 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

EC₅₀/LC₅₀ in marine water sediment: 14 989 mg/kg dw (according to test on *Corophium volutator* according to OSPARCOM guidelines (1995) A sediment Bioassay using an amphipod *corophium* sp); EC₁₀/LC₁₀ or NOEC in freshwater sediment: 10 000 mg/kg sediment dw (according to test on *Hyalella azteca* according to ASTM E1706).

Toxicity to soil macro-organisms

Long-term EC₁₀/LC₁₀ or NOEC for soil arthropods: 1 000 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 EC₁₀/LC₁₀ or NOEC for terrestrial plants: 10 000 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 EC₁₀/LC₁₀ or NOEC for soil micro-organisms: 10 000 mg/kg soil dw (tested on species/*Inoculum*: soil, according to ISO 14238).

Toxicity to aquatic micro-organisms in sewage treatment systems

EC₁₀/LC₁₀ or NOEC for aquatic micro-organisms: 1 000 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

Non-persistent. Decomposition and solubility – see section 09.

12.3 Bioaccumulative potential

Aquatic bioaccumulation:

Ti concentrations in various fish tissues stayed constant over the concentration range of TiO₂ in water tested (0÷1 mg TiO₂/l), resulting in decreasing BCF with increasing TiO₂ concentrations. The substance is not considered as bioaccumulative.

Terrestrial bioaccumulation:

No reliable results are available for the bioaccumulation of TiO₂ in terrestrial organisms. Read-across approach pointed the absence of bioaccumulation of Ti in plants due to equilibrium conditions for Ti in the environment.

12.4 Mobility in soil

The substance is not mobile in soil.

12.5 Results of PBT and vPvB assessment

Negative. The substance is not PBT and vPvB

12.6 Other adverse effects

None other adverse effects 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

13.1 Waste treatment methods

Waste disposal: Dispose of in compliance with local and national regulations.

Residue: EWC Code 06 11 99, for TiO₂ manufacture or other according to origin of waste. Not classified as hazardous waste.

Contaminated packaging: Contaminated packages are not considered hazardous. If recycling is not practicable, dispose of in compliance with local regulations.

SECTION 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 MARPOL 73/78 and the IBC Code

No limitations.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
EU Regulation (EC) No. 1907/2006 (REACH) Annex XVII – Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles, in valid wording, is not applicable.

There is no legal obligation to provide a safety data sheet for hereby referred 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 Labour 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 TiO₂ 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.

15.2 Chemical safety assessment

Chemical safety assessment was carried out by the producer.

SECTION 16: Other information

Advice on training appropriate for workers to ensure protection of human health and the environment: Respect main rules for handling with chemicals.

Revision/Update: This Safety Data Sheet is revised by the manufacturer after every 12 month after the date of validity. 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.

This sheet is based on information:

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 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

Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Safety Data Sheets of raw material suppliers

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)

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

- ★ *not relevant and/or not applicable legal and/or other requirements and/or qualitative attributes of the product, are stated as „not relevant“, „not applicable“ or „N/A“ 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 quality and cannot be used for complaints;*
- ★ *former application tests are necessary before any use of the product;*
- ★ *all relevant and known regulations and rules for handling with chemical substances have to be kept in case of use, handling and/or transport the product;*
- ★ *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 product is used by incompetent manner and/or in applications other than recommended and/or identified;*
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