

SAFETY DATA SHEET

according to Commission Regulation (EU) No. 2020/878

PRETIOX (pigment form)

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

1.1 Product identifier

The product in question, PRETIOX, is a chemical substance based on titanium dioxide (TiO₂).

Product names: **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

Recommended uses: Pigment

Uses not recommended: None

Importer/distributor in CZ:

Ekokoza s.r.o.
Fryčovice 297, 73945, Fryčovice ID: 07508247,
eshop@ekokoza.cz

1.4 Telephone number for emergency situations

Emergency phone number: +420224919293 +420224915402 (phone 24 hours a day)

Toxicology Information Center, Na Bojišti 1, 128 08 Prague 2) or +420 224 915 402 (24/7)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No. 1272/2008 (CLP)

The substance is not classified.

2.1.2 Additional Information

Commission Delegated Regulation (EU) 2020/217 classified titanium dioxide (TiO₂) in powder form containing 1% or more of particles with an aerodynamic diameter $\geq 10 \mu\text{m}$ as a category 2 inhalation carcinogen. Particle analysis confirms that there is no classification requirement for the above-mentioned product PRETIOX (pigment form).

2.2 Marking elements

Signal Word: None

Warning symbol: None

H phrases: None

P phrases: None

2.3 Other hazards

Hazardous respirable dust can be formed when the powdered substance is used.

Based on available data, the substance does not meet the criteria for persistent, bioaccumulative and toxic or highly persistent and highly bioaccumulative substances and does not have endocrine disrupting properties.

SECTION 3: Composition/information on ingredients

3.1 Substances

Main substance component: Titanium dioxide TiO₂, CAS 13463-67-7, EINECS 236-675-5, index number 022-006-002, REACH registration number 01-2119489379-17-0013

3.2 Mixtures

ON

SECTION 4: First aid measures

4.1 Description of first aid

General: In case of persistent problems, call a doctor.

Inhalation: Move the affected person to fresh air and keep him at rest in a position that facilitates breathing, do not let him walk. Secure him against cold, loosen his tight clothing, collar, tie or belt. Rinse his mouth and nose with water.

Contact with skin or hair: Wash affected area with soap and water. Remove all contaminated clothing and wash before reuse.

Contact with the eye: Flush the affected person's eye with a stream of running water. Open the eyelids and if the affected person has contact lenses, remove them. Wash for at least 10 minutes from the inner corner of the eye to the outer corner.

Ingestion: No adverse health effects are expected. Do not induce vomiting. Rinse the victim's mouth with water and give him 2 to 3 dL of water to drink. Do not give anything by mouth if the victim is unconscious.

4.2 Most important symptoms and effects, both acute and delayed

They are not known based on available data.

4.3 Indication of immediate medical attention and special treatment

Not known based on available data.

SECTION 5: Firefighting measures

5.1 Fire extinguishers

Suitable extinguishing media: Water spray/spray, foam, powder, CO₂. The product is not flammable.

Unsuitable extinguishing agents: None known based on available data.

5.2 Special hazards arising from the substance or mixture

Based on the available data, it is not known.

Hazardous combustion products: None known based on available data.

5.3 Instructions for firefighters

Use appropriate personal protective equipment, see SECTION 8.

SECTION 6: Accidental release measures

6.1 Personal protection measures, protective equipment and emergency procedures

No special precautions or training are required. Use appropriate personal protective equipment, see SECTION 8. Prevent unauthorized access. There is a danger of slipping on spilled wet material.

6.2 Environmental protection measures

Seal off the leak and prevent the substance from leaking into the surrounding environment, soil, waterways and sewers with suitable absorbent material (sand, gravel). Inform the relevant authorities if sewage, waterways, soil or atmosphere are contaminated.

6.3 Methods and material for containment and cleaning up

See SECTION 13.

6.4 Reference to Other Sections

Emergency telephone number see SECTION 1. Limiting personal exposure see SECTION 8.

See SECTION 13 for disposal instructions.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Warning: Not known based on available data.

Handling: Observe hygienic requirements for handling chemical substances and mixtures.

Do not eat, drink, smoke or chew in the workplace. Remove contaminated clothing appropriately and wash before reuse. Wash your hands after work. Remove contaminated clothing and personal protective equipment before entering dining areas.

Recommendations for users: Operating personnel must be competent by education and training.
 Engineering measures: Keep production and processing lines closed to limit potential leaks. Use dust reduction equipment when filling transport containers. When handling large volumes of material, use special catch and clean tubs/sinks. If the product packed in bags, apply local operational safety regulations for handling bags.

7.2 Conditions for safe storage of substances and mixtures, including incompatible substances and mixtures
 Do not store outdoors, exposed to the elements. Avoid getting wet.
 Recommended packaging materials: Store in original packaging.
 Incompatible materials: None known based on available data.

7.3 Specific end/specific end uses
 Based on the available data, they are not known.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

General: Provide adequate ventilation. Reduce the risk of inhalation. Follow the exposure limits given in the local guidelines. Use personal protective equipment and apply hygiene and safety rules.

DAYS:

Type	Exposure route	TODAY	Unit
Chronic	Inhalation	10	mg/m3

PNEC:

Type	PNEC	Unit
Aqua (freshwater)	0.127	mg/L
Aqua (sea water)	1	mg/L
Aqua (occasional leaks)	0.61	mg/L
Sediment (freshwater)	1000	mg/kg sediment dw
Sediment (seawater)	100	mg/kg sediment dw
Soil	100	mg/kg soil dw
Waste water treatment plant	100	mg/L
Oral, mammals	1667	mg/kg food

8.2 Limiting Exposure

8.2.1 Appropriate technical controls

Depending on local regulations, an assessment of the effectiveness of ventilation or other measures and/or the use of personal respiratory protective equipment may be required.

8.2.2 Individual protective measures including personal protective equipment

General: Personal protective equipment must correspond to the nature of the work performed, taking into account the risks, and must be approved in advance by a professional specialist.

Eye and face protection: Wear suitable safety glasses or a face shield.

Skin protection: Use protective gloves and protective clothing.

Respiratory protection: In case of increased dust formation, use a respirator or half-mask with a B/P2 filter.

Thermal hazard: Not known based on available data.

Hygienic measures: People with sensitive skin are advised to use a protective moisturizing cream when working.

8.2.3 Limiting environmental exposure

Avoid release to the environment. Monitor emissions from ventilation and operating equipment to ensure compliance with environmental protection requirements. In some cases, it may be necessary to use scrubbers, filters or other technical modifications of the equipment to reduce emissions to the permissible limit.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties a) Physical state (20 °C, 1013 hPa): Solid substance, fine crystalline powder b) Color: White c) Odor: Not known based on available data d) Melting point/freezing point (°C): >1560 e) Boiling point or initial boiling point and boiling point range (°C): approx. 3000 f) Flammability: Not known based on available data g) Lower and upper explosive limits: Not relevant based on available data h) Flash point: Based on available data not relevant i) Autoignition temperature: Based on available data not relevant j) Decomposition temperature: Based on available data not relevant k) pH (at 20 °C): Based on available data not relevant l) Kinematic viscosity: Not relevant based on available data m) Solubility: in water at 20 °C <1 g/L in the pH range 6 to 8 n) Partition coefficient n-octanol/water: Not relevant based on available data o) Vapor pressure : Not relevant based on available data p) Density and/or relative density (at 20 °C): 3900 to 4260 kg/m³ ; loose 500 to 1040

kg/m³ ; crushing 780 to 1200 kg/m³

q) Relative vapor density: Not relevant based on available data r) Particle characteristics: Average primary particle size is greater than 100 nm (ascertained by TEM/SEM)

9.2 Other information a)

Evaporation rate: Not relevant based on available data b) Explosive properties: Not known based on available data c) Oxidizing properties: Not known based on available data

SECTION 10: Stability and reactivity

10.1 Reactivity

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

10.2 Chemical stability Based

on available data, the substance is stable under normal conditions.

10.3 Possibility of hazardous reactions Not

known based on available data.

10.4 Conditions to avoid Wetting.

10.5 Incompatible materials None

known based on available data.

10.6 Hazardous decomposition products None

known based on available data.

SECTION 11: Toxicological information

11.1 Information on hazard classes defined in Regulation (EC) No. 1272/2008 a) Acute toxicity: oral LD₅₀ >5000 mg/kg; inhalation LC₅₀ >6.82 mg/L air (MMAD=1.55 µm, GSD=1.70 µm). Based on the available data, the classification criteria are not met. b) Skin corrosion/irritation: according to the OECD Guideline 404 test, the substance is not irritating. Based on available data, the criteria for classification are not met. c) Serious eye damage / eye irritation: according to OECD Guideline 405, EU Method B.5 and EPA OPPTS 870.2400 tests, the substance does not cause serious eye damage / eye irritation. Based on the available data, the classification criteria are not met.

- d) Respiratory sensitization / skin sensitization: according to OECD Guidelines 406 and 429 tests, it has no substance skin sensitizing ability; the substance also did not show sensitizing properties for the respiratory system pathways in animal studies or human exposure observations. Based on available criteria for classification are not met.
- e) Mutagenicity in germ cells: the substance was tested (bacterial reverse mutation assays, in vitro gene mutation, clastogenicity tests) with a negative result. Based on available criteria for classification are not met.
- f) Carcinogenicity: Commission Delegated Regulation (EU) 2020/217 classified the oxide titanium dioxide (TiO₂) in powder form containing 1% or more particles of aerodynamic diameter $\geq 10 \mu\text{m}$ as a category 2 carcinogen by inhalation. The substance is listed below on the IARC list as a possible human carcinogen (group 2B). Detailed however, epidemiologic studies have not shown an association between exposure to the substance and cancer risk.
- g) Reproductive toxicity: Depending on the strength of evidence from available long-term studies on toxicity/carcinogenicity in rodents and relevant toxicokinetic behavior in rats is not a substance toxic for reproduction. Based on the available data, the classification criteria are not met.
- h) Specific target organ toxicity - single exposure: No reversible effects were observed or irreversible effects after oral exposure immediately or delayed after exposure. Based on available data, the criteria for classification are not met.
- i) Specific target organ toxicity - repeated exposure: The substance did not show any adverse effects in a repeated-dose chronic oral toxicity study in rats with a NOAEL 3500 mg/kg/day; the substance is not absorbed to any relevant extent by human skin so no toxic effects can be expected through the dermal route of exposure; by the inhalation route of exposure the following have been done in animal experiments and epidemiological studies observations: (i) No systematic toxicity resulting from chronic inhalation exposure of high concentrations of pigmented titanium dioxide in rats have not been demonstrated, (ii) Particulate overload is observed for insoluble particles such as titanium dioxide to which the rat is most sensitive species studied; species-specific have been demonstrated in various mechanistic studies differences. It has been shown with reasonable certainty that conditions of pulmonary congestion are not relevant for human health and therefore results based on such data do not warrant classification, (iii) There were also epidemiological studies for workers exposed to titanium dioxide proven to be no causal relationship. Based on available data, there are no criteria for classification met.
- j) Aspiration hazard: Based on available data, there are no classification criteria fulfilled.

11.2 Information on additional hazards

They are not known based on available data.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to aquatic organisms acute - fish All reliable

acute toxicity tests on fish (4 different species in fresh and salt water) resulted in LC₅₀ values ranging from >1 to >10000 mg TiO₂/L. Using a weight-of-evidence approach, the substance was defined as not acutely toxic to fish at >1000 mg TiO₂/L in freshwater and at >10000 mg TiO₂/L in seawater.

Results of acute toxicity tests on fish:

Pimephales promelas LC₅₀ (96 h): >1000 mg/L, tested according to EPA-540/9-85-006, Acute Toxicity Test for Freshwater Fish *Oncorhynchus*

mykiss LC₅₀ (96 h): >100 mg/L, tested in fresh water, according to OECD Guideline 203 (Fish, Acute Toxicity Test *Oncorhynchus mykiss* LC₅₀ (14

d): >1 mg/L, tested in fresh water, where fish were exposed to different concentrations of the test material and then biochemical characteristics of different organs were measured

Danio rerio LC₅₀ (48 h): >10 mg/L, tested in fresh water, according to American Society of Testing and Materials (ASTM), 2002 *Cyprinodon*

variegatus LC₅₀ (96 h): >10000 mg/L, tested in sea water, according to OECD Guideline 203 (Fish, Acute Toxicity Test) and according to OSPARCOM (2005-11), Protocol for a fish acute toxicity test.

Toxicity to aquatic organisms acute - invertebrates

All reliable acute toxicity tests on invertebrates (4 different species in fresh and salt water) resulted in L(E)C50 values from >10 to >10000 mg TiO₂/L. Using a weight-of-evidence approach, the substance was defined as not acutely toxic to invertebrates at >1000 mg TiO₂/L

in freshwater and at >10000 mg TiO₂/L in seawater.

Results of acute toxicity tests on invertebrates:

Daphnia magna LC50 (48 h): >100 mg/L, tested in fresh water, according to OECD Guideline 202 (*Daphnia* sp. Acute Immobilization Test)

Daphnia pulex LC50 (48 h): >10 mg/L tested in fresh water, according to the American Society for Testing and Materials: Standard guide for conducting acute toxicity tests on test materials with fishes, macro invertebrates and amphibians.

Ceriodaphnia dubia LC50 (48 h): >10 mg/L tested in fresh water, according to the American Society for Testing and Materials: Standard guide for conducting acute toxicity tests on test materials with fishes, macro invertebrates and amphibians.

Daphnia magna EC50 (48 h): >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 US Environmental Protection Agency (660/3-75-009), 1975: Methods for Acute Toxicity Tests with Fish, Macro-invertebrates and Amphibians

Daphnia magna LC50 (48 h): >500 mg/L tested in fresh water, according to US EPA standard operating procedure 2024

Acartia tonsa LC50 (48 h): >10000 mg/L, tested in salt 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

Chronic toxicity to aquatic organisms

The results of reliable tests are not known. However, since all acute tests show the absence of toxic effects, no further testing is necessary for the substance.

Toxicity to algae and aquatic plants

The lowest value for algae was recorded for *Pseudokirchneriella subcapitata* in fresh water: EC50 (72 h) 61 mg/L (growth rate, test according to OECD Guideline 201 (Alga, Growth Inhibition Test) with a corresponding EC10 (72 h) 12.7 mg TiO₂ / L. Tests with *Skeletonema costatum*

in seawater resulted in EC50 >10000 and NOEC 5600 mg TiO₂/L (growth rate, test according to ISO 10253 (Water quality – Marine Algal Growth Inhibition Test with *Skeletonema costatum* and *Phaeodactylum tricornutum*).

Toxicity to sedimentary organisms

EC50/LC50 for marine water sediment: 14989 mg/kg (according to the test on *Corophium volutator* according to OSPARCOM guidelines (1995) A sediment Bioassay using an amphipod *Corophium* sp.);

EC10/LC10 or NOEC freshwater sediment: 100000 mg/kg sediment (according to *Hyalella azteca* test according to ASTM E1706).

Toxicity to soil macro-organisms

Long-term EC10/LC10 or NOEC for soil arthropods: 1000 mg/kg soil (tested for *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: 100000 mg/kg soil (tested on *Hordeum vulgare* (*Monocotyledonae* (*monocots*)) and *Lactuca sativa* (*Dicotyledonae* (*dicots*))), according to ISO 11269-2 protocol).

Toxicity to soil microorganisms

Long-term EC10/LC10 or NOEC for soil microorganisms: 10000 mg/kg soil (tested for species/Inoculum: soil, according to ISO 14238).

Toxicity to aquatic microorganisms in wastewater treatment plants

EC10/LC10 or NOEC aquatic microorganisms: 1000 mg/L (activated sludge tested mainly domestic waste, in fresh water, according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test).

12.2 Persistence and Deployability

Based on available data, the substance is not considered to be persistent and degradable.

12.3 Bioaccumulative potential

Based on the available data, the substance is not considered to be bioaccumulative.

12.4 Mobility in soil

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

12.5 Results of PBT and vPvB assessment

Based on the available data, the substance is not considered to be PBT or vPvB.

12.6 Endocrine-disrupting properties None known based on available data.

12.7 Other adverse effects

None known based on available data.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product residues/degraded product: Check possible reuse. Package, label and dispose or recycle in accordance with national and local regulations. In the case of larger volumes, consult the manufacturer for handling.

Contaminated packaging: Not considered hazardous waste based on current knowledge. If you pass them on, their recipient must be made aware of the risks arising from material residues. If recycling is not possible, dispose of them in accordance with national and local regulations.

Hazardous waste: Based on current knowledge, the substance is not considered hazardous waste, EWL code 06 11 99.

SECTION 14: Transport information

14.1 UN number or ID number

Not relevant based on available data.

14.2 Official (UN) proper shipping name Not relevant based on available data.

14.3 Transport hazard class(es) Not relevant based on available data.

14.4 Packing group Not relevant based on available data.

14.5 Environmental hazards Not relevant based on available data.

14.6 Special security measures for users. Not relevant based on available data.

14.7 Bulk transport according to IMO instruments

The substance is not intended for transport as bulk cargo according to IMO instruments.

SECTION 15: Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific to the substance or mixture Based on the available information, there are no known Union safety, health and environmental regulations applicable to the substance listed in this safety data sheet.

There is no legal obligation to provide a safety data sheet for the given substance.

15.2 Chemical safety assessment The manufacturer has carried out a chemical safety assessment.

Exposure assessment: Based on the available data, the product is not considered dangerous and 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 product is not considered dangerous and does not meet the PBT and vPvB criteria, so there is no obligation to carry out a risk characterization.
Exposure scenarios are not relevant for the given substance.

SECTION 16: Further information

Revision and update of this safety data sheet

The manufacturer revises this safety data sheet every 12 months, starting from the date of validity or as soon as new information is available that may affect risk management measures or new hazard information or after granting/refusal of authorization/imposing restrictions.

If this safety data sheet is satisfactory, it will keep it in use without further ado, including on its website www.ekokoza.cz

If it doesn't match, it updates it and re-releases with a release number one higher.

Changes compared to the previous version of the safety data sheet

SECTION 2: Hazard Identification; SECTION 9: Physical and chemical properties; SECTION 11: Toxicological information; SECTION 12: Ecological information; SECTION 14 Shipping Information; SECTION 16: Further information.

Key/legend to abbreviations and acronyms used in this safety data sheet

DNEL derived level of exposure at which adverse effects on human health do not occur

PNEC predicted concentration at which adverse effects on human health do not occur

Important literature references and data sources

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 on the registration, evaluation, authorization and restriction of chemical substances, on the establishment of the European Chemicals Agency, on the amendment of Directive 1999/45/EC and on the repeal of the Council Regulation (EEC) No. 793/93, Commission Regulation (EC) No. 1488/94, Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Commission Regulation (EU) No. 2020/878 amending Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemical Substances

Regulation of the European Parliament and of the Council (EC) No. 1272/2008 on the classification, labeling and packaging of substances and mixtures, on the amendment and repeal of Directives 67/548/EEC and 1999/45/EC and on the amendment of Regulation (EC) No. 1907/2006

Act No. 185/2001 Coll. on waste, as amended

Act No. 254/2001 Coll. on waters, as amended

Act No. 262/2006 Coll. Labor Code, as amended

Act No. 309/2006 Coll. on ensuring other conditions of safety and health protection at work, as amended

Government Regulation No. 361/2007 Coll., establishing the conditions for health protection at work, as amended

Safety data sheets of raw material suppliers

Safety data sheets of similar products

ECHA documentation

PhysProp database; <http://esc.syrres.com/interkow>

Ecotoxicology database; <http://www.piskac.cz/ETD>

ICSC Database (WHO/IPCS/ILO); <http://www.cdc.gov/niosh/ipcs>

Chemical Safety Report, Titanium Dioxide, TiOxide Europe Limited, (2010)

Information evaluation method according to Article 9 of Regulation (EC) No. 1272/2008 for the purpose of classification of mixtures

Annex I of Regulation (EC) No. 1272/2008

List of relevant hazard statements and/or safety instructions

ON

Guidance on all training intended for workers ensuring the protection of human health and the environment

Follow all policies applicable to handling chemicals and chemical mixtures.

Postscript

The product described in this document is intended only for professional industrial or related use (eg research and development) by qualified persons.

All information provided herein is provided in good faith, provided that:

• non-applicable legal or other requirements or features of the product are marked as "not relevant" or "N/A" in the safety data sheet. Values of product requirements or features that are not known to the suppliers of this safety data sheet are marked as "not known" in this safety data sheet, in any gender, number and case;

• contain the current state of scientific knowledge with regard to the legitimate interest and requirements of occupational safety and hygiene;

• are not a guarantee of the quality of the product and cannot be used when claiming goods;

• the manufacturer always recommends performing preliminary application tests

• the manufacturer warns the user to observe all generally applicable principles for handling chemical substances and mixtures;

• the use of this information and the use of the product is not controlled by the manufacturer, therefore the manufacturer does not accept responsibility for injuries or damages caused by unprofessional, incorrect or unapproved use of the product;

• the user is responsible for respecting all industrial and patent rights associated with the product.

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