

**Pretiox AV-01-FG - Food/Pharma Grade**



**PRETIOX**



# PRETIOX AV-01-FG

## FOOD/PHARMA GRADE

### DESCRIPTION

PRETIOX AV-01-FG is uncoated high purity anatase easy dispersed pigment with high brightness and good opacity.

### IDENTIFICATION

<b>Chemical name</b>	Titanium dioxide
<b>Chemical formula</b>	TiO <sub>2</sub>
<b>Molecular weight</b>	79,88
<b>CAS No.</b>	13463-67-7
<b>EINECS and TSCA No.</b>	236-675-5
<b>Colour Index</b>	77891
<b>Colour Name</b>	Pigment White 6

### APPLICATION

Pigmentation of foodstuffs, pharmaceuticals, cosmetics, etc.

- **Foodstuffs:** colorant for sugar products, candy, chewing gum, coffee whitener.
- **Pharmaceuticals:** coloring agent for capsules, films, tablets and coated pills, medical sticky tapes.
- **Cosmetics:** for high quality eye and face make-ups, lipsticks, nail lacquers, toothpastes.
- **Other application:** cigarettes and cigars - filter wrappings, tips and filter tipping papers, pet-foods

### CHARACTERISTICS

<b>ISO 591 classification</b>	A1
<b>ASTM D-476-84 classification</b>	I
<b>TiO<sub>2</sub> content (min.)</b>	99,0 %
<b>Inorganic coating</b>	none
<b>Organic treatment</b>	none
<b>Specific density</b>	3,8 g/cm <sup>3</sup>
<b>Refractive index (approx.)</b>	2,5

### MICROBIOLOGY

#### 1. Determination of the total viable aerobic count

The determination of the number of bacteria and moulds is performed in German Institute ISEGA according to the European Pharmacopoeia 2.6.12 by means of the plate-count. The analysis was performed with 10 g of samples with following results:

<b>Bacteria</b>	< 10 cfu/g
<b>Moulds</b>	< 10 cfu/g
<b>Yeasts</b>	< 10 cfu/g

(cfu/g = colony forming units per gramm sample)

#### 2. Examination for specified microorganisms

The detection of specified microorganisms was carried (in ISEGA) according to European Pharmacopoeia 2.6.13. The analysis was performed with 10 g of sample with following result:

<b>Enterobacteriaceae</b>	not detected
<b>Escherichia coli</b>	not detected
<b>Salmonella</b>	not detected
<b>Pseudomonas aeruginosa</b>	not detected
<b>Staphylococcus aureus</b>	not detected
<b>Clostridia</b>	not detected



### PURITY STANDARDS

PRETIOX AV-01-FG meets the chemical purity specifications of the major pharmacopoeia and the EEC and US federal requirements for dyestuff in the food and cosmetics sector:

<b>Commission Directive 95/45/EC</b>	E171
<b>FDA Regulation 21 CFR</b>	73.575 (Foods) 73.1575 (Drugs) 732575 (Cosmetics)
<b>European Pharmacopoeia</b>	Ph.Eur.
<b>Pharmacopoeia of the USA</b>	USP/NF

#### 1) Purity requirements for direct addition to human food

a) in Europe

	<b>E-171</b>	<b>AV-01-FG typical</b>
<b>TiO<sub>2</sub> content [%]</b>	min. 99,00	99,30
<b>Loss on drying [%]</b>	max. 0,50	0,30
<b>Loss on ignition [%]</b>	max. 0,50	0,30
<b>Al<sub>2</sub>O<sub>3</sub> and/or SiO<sub>2</sub> [%]</b>	max. 2,00	0,05
<b>Acid soluble salts [%]</b>	max. 0,50	0,40
<b>Water soluble salts (hot) [%]</b>	max. 0,50	0,35
<b>Cadmium (total content) [mg/kg]</b>	max. 1,00	< 1,00
<b>Antimony (total content) [mg/kg]</b>	max. 50,00	25,00
<b>Arsenic (total content) [mg/kg]</b>	max. 3,00	1,00
<b>Lead (total content) [mg/kg]</b>	max. 10,00	6,00
<b>Mercury (total content) [mg/kg]</b>	max. 1,00	0,10
<b>Zinc (total content) [mg/kg]</b>	max. 50,00	5,00

b) in the United States

	<b>FDA 21 CFR</b>	<b>AV-01-FG typical</b>
<b>TiO<sub>2</sub> content [%]</b>	min. 99,00	99,30
<b>Loss on ignition [%]</b>	max. 0,50	0,30
<b>Al<sub>2</sub>O<sub>3</sub> and/or SiO<sub>2</sub> [%]</b>	max. 2,00	0,05
<b>Acid soluble salts [%]</b>	max. 0,50	0,40
<b>Water soluble salts (hot) [%]</b>	max. 0,50	0,22
<b>Antimony (HCl soluble) [mg/kg]</b>	max. 2,00	< 2,00
<b>Arsenic (HCl soluble) [mg/kg]</b>	max. 1,00	< 1,00
<b>Lead (HCl soluble) [mg/kg]</b>	max. 10,00	5,00
<b>Mercury (HCl soluble) [mg/kg]</b>	max. 1,00	0,10

## 2) Purity requirements for pharmaceutical application

a) in Europe

	Ph.Eur.	AV-01-FG typical
<b>Characters</b>	White powder	complies
<b>Identification</b>	A. pale yellowish colour at heating	complies
	B. orange-red colour with H <sub>2</sub> O <sub>2</sub>	complies
	C. violet-blue colour with zinc	complies
<b>Tests</b>		
<b>Appearance of solution</b>	colourless, not more opalescent than reference solution	complies
<b>Acidity or alkalinity</b>	nmt 1.0 ml 0,01 M HCl or 0,01 M NaOH	complies
<b>Water-soluble substances</b>	max. 25 mg	16 mg
<b>Antimony (HCl soluble)</b>	max. 100 ppm	< 0.2 ppm
<b>Arsenic (HCl soluble)</b>	max. 5 ppm	< 0.2 ppm
<b>Barium</b>	not more opalescent than reference	complies
<b>Heavy metals (HCl soluble)</b>	max 20 ppm	complies
<b>Iron</b>	max 200 ppm	complies
<b>Assay</b>	more than 98.0 and nmt 100.5 %	98,6 %

b) in the United States

	USP/NF	AV-01-FG typical
<b>Identification</b>	yellow-red to orange-red colour with H <sub>2</sub> O <sub>2</sub>	complies
<b>Loss on drying</b>	max 0,5 %	< 0,1 %
<b>Loss on ignition</b>	max. 0,5 %	0,3 %
<b>Water-soluble substances</b>	max 0,25 %	0,22 %
<b>Acid-soluble substances</b>	max. 0,5 %	0,2 %
<b>Assay</b>	99,0 – 100,5 % TiO <sub>2</sub>	99,5 %
<b>Arsenic (HCl soluble)</b>	max. 1 ppm	18 ppb
<b>Organic volatile impurities</b>		
<b>Chloroform</b>	60 ug per g	< 1 ug per g
<b>1,4-Dioxane</b>	380 ug per g	< 20 ug per g
<b>Dichlormethane</b>	600 ug per g	< 1 ug per g
<b>Trichlorethylene</b>	80 ug per g	< 1 ug per g

### PACKAGING

PRETIOX AV-01-FG is standardly packed in twofold vent paper bags for 25 kg net weight each or in big-bags for 1000 kg net. AV-01-FG is delivered on disposable wooden palette (each palette 1 tonne), paletts are covered with polyethylene shrinking foil.

Special packaging and labeling can be agreed on request.

### SAFETY, HEALTH AND ENVIRONMENT

Titanium dioxide PRETIOX is stable under normal condition and inert to most chemical substances. Titanium dioxide generally is not classified as hazardous to human health or to the environment and is also non-hazardous substance for transport. In handling of PRETIOX AV-01-FG dusting of the pigment is possible. In long-term exposure of dust, suitable dust respirators should be used. PRECOLOR provides customers with Safety Data Sheet in accordance with EEC regulation.



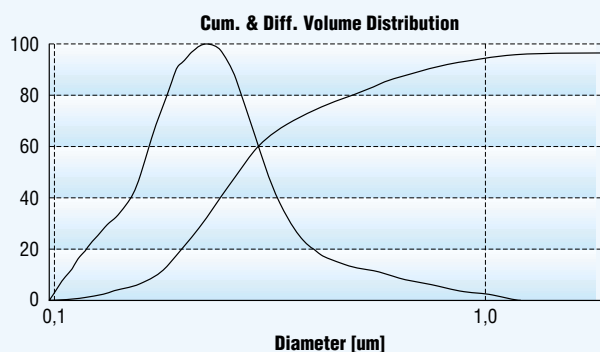
### QUALITY

PRETIOX AV-01-FG is suitable for use in products relating to human health. Suitability for foodstuffs and cosmetics is approved by German Institute ISEGA. Microbiological tests according European and US Pharmacopoeia confirm safety of AV-01-FG for human health. Conformity with European and US Pharmacopoeia is approved by German Institute FRESINIUS.

PRETIOX AV-01-FG is KOSHER (Pareve and for Passover) and under supervision of Star-K Kosher Certification, Maryland, USA.

The manufacture and sales of PRETIOX AV-01-FG is within the scope of ISO 9001 certified Quality Management System. The Precheza production plant has also an ISO 14001 certified Environmental Management System.

### Typical Particle – Size Distribution



Cum. Distribution			
% less	Size [mm]	% less	Size [mm]
1	0,119	60	0,301
10	0,176	70	0,363
20	0,201	80	0,496
30	0,225	90	0,745
40	0,246	99	1,000
50	0,270		



**TiO<sub>2</sub>**



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This technical literature is not intended for German market.  
Additional technical information are available on request in our Technical and Marketing Centre.