

Product description:
HOMBITAN AFDC 101

Date of manufacture: 25.06.2022

Best before: 24.06.2025

Manufacturer & tested by:
Venator Germany GmbH
Dr.-Rudolf-Sachtleben-Str. 4,
D-47198 Duisburg,
Germany

Delivered board numbers:

D2FR44/09, D2FR44/10, D2FR44/11, D2FR44/12, D2FR44/13, D2FR44/14, D2FR44/15, D2FR44/16, D2FR44/17, D2FR44/18.

CERTIFICATE OF ANALYSIS

E-Mail: Customer_Service_Specialties1@venatorcorp.com
Customer_Service_Specialties2@venatorcorp.com
Customer_Service_Specialties@venatorcorp.com
TioxideUS_Customer_Services@venatorcorp.com

Customer Purchase order no: 212-11901-OP

Sales order no: 631112

Delivery no: 81116763

Customer no: 34567

Product code: AFDC101_AA

Delivery quantity: 10,000 kg

Batch number: D2FR440019

AFDC101_1; AFDC101_903; 300000130180644; 6.9.2022; 2.3

Kli 105

Test parameter	Unit	Method	Test value	Lower limit	Upper Limit	Reference
Titanium Dioxide	%	S-1008	99,1	99,0	100,5	USP
Identity		C101206	meets spec			USP/EP/IP
Loss on drying	%	S-1003A	0,1		0,5	USP
Loss on ignition	%	S-1004A	0,1		0,5	USP
Water-soluble substances	%	B318-01	0,20		0,25	USP
Acid-soluble substances	%	B318-02	0,3		0,5	USP
Arsenic (total)	mg/kg	C101-126	< 1		1	USP
Lead (HCl-soluble)	mg/kg	C101130	< 10		10	USP
Antimony (HCl-soluble)	mg/kg	C101130	< 2		2	USP
Mercury (total)	mg/kg	C101107A	< 1		1	USP
Titanium Dioxide	%	S-1008	99,1	99,0		FDA
Loss on ignition	%	S-1004A	0,1		0,5	FDA
Water soluble substances	%	B318-01	0,2		0,3	FDA
Acid-soluble substances	%	B318-02	0,3		0,5	FDA
Arsenic (HCl-soluble)	mg/kg	C101130	< 1		1	FDA
Lead (HCl-soluble)	mg/kg	C101130	< 10		10	FDA
Antimony (HCl-soluble)	mg/kg	C101130	< 2		2	FDA
Mercury (total)	mg/kg	C101107A	< 1		1	FDA
Al2O3 and/or SiO2	%	S-1008	< 2		2	FDA
Titanium Dioxide	%	S-1008	99,1	99,0		E171
Loss on drying	%	S-1003A	0,1		0,5	E171
Loss on ignition	%	S-1004A	0,1		1,0	E171
Water soluble substances	%	B318-01	0,2		0,5	E171
Acid-soluble substances	%	B318-02	0,3		0,5	E171

PT. HENSAN BERSAMA SUKSES
INDONESIA

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Customer no: 34567

Product code: AFDC101_AA

Delivery quantity: 10,000 kg

Batch number: D2FR440019

AFDC101_1; AFDC101_905; 300000130100644; 6.9.2022; 2.3

KII / 05

Test parameter	Unit	Method	Test value	Lower limit	Upper Limit	Reference
Al ₂ O ₃ and/or SiO ₂	%	S-1008	< 2,0		2,0	E171
Arsenic (HCl-soluble)	mg/kg	C101130	< 1		1	E171
Lead (HCl-soluble)	mg/kg	C101130	< 1		10	E171
Antimony (HCl-soluble)	mg/kg	C101130	< 2		2	E171
Mercury (HCl-soluble)	mg/kg	C101130	< 1,0		1,0	E171
Cadmium (HCl-soluble)	mg/kg	C101130	< 1,0		1,0	E171
Nano Content by number (calc.)	%	FT050100	6		19	E171
Titanium Dioxide	%	S-1008	99,1	98,0	100,5	EP
Identity		C101206	meets spec			USP/EP/JP
Water soluble substances	%	B318-01	0,2		0,5	EP
Arsenic (total)	mg/kg	C101-126	< 1		1	EP
Antimony (total)	mg/kg	C101-126	< 1		2	EP
Barium (total)	mg/kg	C101-126	< 20		20	EP
Iron (total)	mg/kg	C101101C	< 200		200	EP
Lead (total)	mg/kg	C101-126	< 1		5	EP
Appearance of solution		C101204	meets spec			EP
Acidity or alkalinity	ml	C101204	< 1,0		1,0	EP
Titanium Dioxide	%	S-1008	99,1	98,5		JP
Identity		C101206	meets spec			USP/EP/JP
Loss on drying	%	S-1003A	0,1		0,5	JP
Water soluble substances	%	B318-01	0,20		0,25	JP
Arsenic (total)	mg/kg	C101-126	< 10		10	JP
Lead (total)	mg/kg	C101101C	< 60		60	JP
Total Yeast and Moulds Count (TYMC)	cfu/g	R200-06	< 100		100	

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Delivery no: 81116763

Customer no: 34567

Product code: AFDC101_AA

Delivery quantity: 10,000 kg

Batch number: D2FR440019

AFDC101_1; AFDC101_905; 3000C0130180644; 5.9.2022; 2.3

Kli / 25

Test parameter	Unit	Method	Test value	Lower limit	Upper Limit	Reference
Total Aerobic Microbial Count (TAMC)	cfu/g	R200-01	< 100		100	
Escherichia coli absent in 1g		R200-12	meets spec			
Pseudomonas aeruginosa absent in 1g		R200-12	meets spec			
Staphylococcus aureus absent in 1g		R200-12	meets spec			
Salmonella spp. absent in 10g		R200-12	meets spec			
Candida albicans absent in 1g		R200-12	meets spec			
Bile tol. Gram neg. Bact. absent in 1g		R200-12	meets spec			
Clostridia absent in 1g		R200-12	meets spec			
pH-value		S-1001	7,0	6,5	8,5	

Appearance: white powder, odourless.

The product meets the specifications of USP, EP, JP, FDA (21 CFR 73.575; 73.1575; 73.2575 and 73.3126), EU (E171 in 231/2012/EC), FCC and JECFA on the date of production. Residual solvents USP < 467 >: No solvents used during manufacture. No animal derived or GMO material used during manufacture.

Shelf-life: HOMBITAN Titanium Dioxides as inorganic compounds are extremely stable if stored dry at ambient temperatures. Therefore no shelf-life is defined. The only possible change could be a decrease in dispersibility due to potential formation of agglomerates. Depending on the application an adequate dispersion has to be taken care of. We recommend using the product within 3 years after production.

The nano-content of nanoparticles by number is calculated by using the correlation between SEM (Scanning Electron Microscopy) measurements and CBU (Carbon Black Untertone) results. Correlation curves can be provided on demand. According to a result of less than 50 % by number the material is not a nanomaterial pursuant to the Commission Recommendation of 18th October 2011 on the definition of nanomaterial, the EU Regulation 2017/45 of April 2017 on Medical Devices, and the French Decree no. 2012-232 of 17th February 2012 on the annual declaration on substances at nanoscale.

The character "c" corresponds to the expression "not more than (nm)" in the mentioned pharmacopoeias. Test values are based on analyses carried out in the Quality Control Laboratory of Venator Germany GmbH promptly after production with the exception of pathogens. Analyses of pathogens are carried out by the laboratories of Henkel AG & Co. KGaA, Düsseldorf.

The material is certified according to FSSC 22000. FDA Registration No. 12754601774

Venator Germany GmbH
Dr.-Rudolf-Sachtleben-Str. 4, D-47198 Duisburg, Germany
Telephone +49 2056 22-0 - Fax +49 2056 22-2000
Sitz der Gesellschaft: D-47198 Duisburg, Amtsgericht Duisburg HR B 19668
VAT Registration No.: DE 814 031 123

Date of Approval:

06. SEP. 2022

Authorised signature:

[Signature]
Head of Quality Control

The Venator Germany GmbH standard terms and conditions of sale shall apply.

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AFDC101_1; AFDC101_905; 300000130180644; 6.9.2022; 2.3

Kli/OS

Test parameter	Unit	Method	Test value	Lower limit	Upper Limit	Reference
Titanium Dioxide	%	S-1008	99,1	99,0	100,5	USP
Identity		C101206	meets spec			USP/EP/IP
Loss on drying	%	S-1003A	0,1		0,5	USP
Loss on ignition	%	S-1004A	0,1		0,5	USP
Water-soluble substances	%	B318-01	0,20		0,25	USP
Acid-soluble substances	%	B318-02	0,3		0,5	USP
Arsenic (total)	mg/kg	C101-126	< 1		1	USP
Lead (HCl-soluble)	mg/kg	C101130	< 10		10	USP
Antimony (HCl-soluble)	mg/kg	C101130	< 2		2	USP
Mercury (total)	mg/kg	C101107A	< 1		1	USP
Titanium Dioxide	%	S-1008	99,1	99,0		FDA
Loss on ignition	%	S-1004A	0,1		0,5	FDA
Water soluble substances	%	B318-01	0,2		0,3	FDA
Acid-soluble substances	%	B318-02	0,3		0,5	FDA
Arsenic (HCl-soluble)	mg/kg	C101130	< 1		1	FDA
Lead (HCl-soluble)	mg/kg	C101130	< 10		10	FDA
Antimony (HCl-soluble)	mg/kg	C101130	< 2		2	FDA
Mercury (total)	mg/kg	C101107A	< 1			FDA
Al2O3 and/or SiO2	%	S-1008	< 2		2	FDA
Titanium Dioxide	%	S-1008	99,1	99,0		E171
Loss on drying	%	S-1003A	0,1		0,5	E171
Loss on ignition	%	S-1004A	0,1		1,0	E171
Water soluble substances	%	B318-01	0,2		0,5	E171
Acid-soluble substances	%	B318-02	0,3		0,5	E171

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Delivery no: 81116763

Customer no: 34567

Product code: AFDC101_AA

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Batch number: D2FH440019

AFDC101_1; AFDC101_905; 300000130180644; 6.9.2022; 2.3

Test parameter	Unit	Method	Test value	Lower limit	Upper Limit	Reference
Al ₂ O ₃ and/or SiO ₂	%	S-1008	< 2,0		2,0	E171
Arsenic (HCl-soluble)	mg/kg	C101130	< 1		1	E171
Lead (HCl-soluble)	mg/kg	C101130	< 1		10	E171
Antimony (HCl-soluble)	mg/kg	C101130	< 2		2	E171
Mercury (HCl-soluble)	mg/kg	C101130	< 1,0		1,0	E171
Cadmium (HCl-soluble)	mg/kg	C101130	< 1,0		1,0	E171
Nano Content by number (calc.)	%	FT050100	5		19	E171
Titanium Dioxide	%	S-1008	99,1	98,0	100,5	EP
Identity		C101205	meets spec			USP/EP/JP
Water soluble substances	%	B318-01	0,2		0,5	EP
Arsenic (total)	mg/kg	C101-126	< 1		1	EP
Antimony (total)	mg/kg	C101-126	< 1		2	EP
Barium (total)	mg/kg	C101-126	< 20		20	EP
Iron (total)	mg/kg	C101101C	< 200		200	EP
Lead (total)	mg/kg	C101-126	< 1		5	EP
Appearance of solution		C101204	meets spec			EP
Acidity or alkalinity	ml	C101204	< 1,0		1,0	EP
Titanium Dioxide	%	S-1008	99,1	98,5		JP
Identity		C101206	meets spec			USP/EP/JP
Loss on drying	%	S-1003A	0,1		0,5	JP
Water soluble substances	%	B318-01	0,20		0,25	JP
Arsenic (total)	mg/kg	C101-126	< 10		10	JP
Lead (total)	mg/kg	C101101C	< 60		60	JP
Total Yeast and Moulds Count (TYMC)	cfu/g	R200-06	< 100		100	

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AFDC101_1; AFDC101_905; 300000130180644; 5.9.2022; 2.3

Kli / 25

Test parameter	Unit	Method	Test value	Lower limit	Upper Limit	Reference
Total Aerobic Microbial Count (TAMC)	cfu/g	R200-01	< 100		100	
Escherichia coli absent in 1g		R200-12	meets spec			
Pseudomonas aeruginosa absent in 1g		R200-12	meets spec			
Staphylococcus aureus absent in 1g		R200-12	meets spec			
Salmonella spp. absent in 10g		R200-12	meets spec			
Candida albicans absent in 1g		R200-12	meets spec			
Bile tol. Gram neg. Bact. absent in 1g		R200-12	meets spec			
Clostridia absent in 1g		R200-12	meets spec			
pH-value		S-1001	7,0	6,5	8,5	

Appearance: white powder, odourless.

The product meets the specifications of USP, EP, JP, FDA (21 CFR 73.575; 73.1575; 73.2575 and 73.3126), EU (E171 in 231/2012/EC), FCC and JECFA on the date of production.
Residual solvents USP < 467 >: No solvents used during manufacture.
No animal derived or GMO material used during manufacture.

Shelf-life: HOMBITAN Titanium Dioxides as inorganic compounds are extremely stable if stored dry at ambient temperatures. Therefore no shelf-life is defined. The only possible change could be a decrease in dispersibility due to potential formation of agglomerates. Depending on the application an adequate dispersion has to be taken care of. We recommend using the product within 3 years after production.

The nano-content of nanoparticles by number is calculated by using the correlation between SEM (Scanning Electron Microscopy) measurements and CBU (Carbon Black Untertone) results. Correlation curves can be provided on demand. According to a result of less than 50 % by number the material is not a nanomaterial pursuant to the Commission Recommendation of 18th October 2011 on the definition of nanomaterial, the EU Regulation 2017/45 of April 2017 on Medical Devices, and the French Decree no. 2012-232 of 17th February 2012 on the annual declaration on substances at nanoscale.

The character "<" corresponds to the expression "not more than (nmt)" in the mentioned pharmacopeias.

Test values are based on analyses carried out in the Quality Control Laboratory of Venator Germany GmbH promptly after production with the exception of pathogens. Analyses of pathogens are carried out by the laboratories of Henkel AG & Co. KGaA, Düsseldorf.

The material is certified according to FSSC 22000. FDA Registration No. 12754601774

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VAT Registration No.: DE 814 031 123

Date of Approval:

06. SEP. 2022

Authorised signature:

J. G. S. S. S.
Head of Quality Control

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Kli / 05

Test parameter	Unit	Method	Test value	Lower limit	Upper Limit	Reference
Titanium Dioxide	%	S-1008	99,1	99,0	100,5	USP
Identity		C101206	meets spec			USP/EP/IP
Loss on drying	%	S-1003A	0,1		0,5	USP
Loss on ignition	%	S-1004A	0,1		0,5	USP
Water-soluble substances	%	B318-01	0,20		0,25	USP
Acid-soluble substances	%	B318-02	0,3		0,5	USP
Arsenic (total)	mg/kg	C101-126	< 1		1	USP
Lead (HCl-soluble)	mg/kg	C101130	< 10		10	USP
Antimony (HCl-soluble)	mg/kg	C101130	< 2		2	USP
Mercury (total)	mg/kg	C101107A	< 1		1	USP
Titanium Dioxide	%	S-1008	99,1	99,0		FDA
Loss on ignition	%	S-1004A	0,1		0,5	FDA
Water soluble substances	%	B318-01	0,2		0,3	FDA
Acid-soluble substances	%	B318-02	0,3		0,5	FDA
Arsenic (HCl-soluble)	mg/kg	C101130	< 1		1	FDA
Lead (HCl-soluble)	mg/kg	C101130	< 10		10	FDA
Antimony (HCl-soluble)	mg/kg	C101130	< 2		2	FDA
Mercury (total)	mg/kg	C101107A	< 1		1	FDA
Al ₂ O ₃ and/or SiO ₂	%	S-1008	< 2		2	FDA
Titanium Dioxide	%	S-1008	99,1	99,0		E171
Loss on drying	%	S-1003A	0,1		0,5	E171
Loss on ignition	%	S-1004A	0,1		1,0	E171
Water soluble substances	%	B318-01	0,2		0,5	E171
Acid-soluble substances	%	B318-02	0,3		0,5	E171



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Batch number:	D2FR440019

AFDC101_1; AFDC101_305; 300000130180644; 6.9.2022; 2.3

Delivered board numbers:
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Test parameter	Unit	Method	Test value	Lower limit	Upper Limit	Reference
Al ₂ O ₃ and/or SiO ₂	%	S-1008	< 2,0		2,0	E171
Arsenic (HCl-soluble)	mg/kg	C101130	< 1		1	E171
Lead (HCl-soluble)	mg/kg	C101130	< 1		10	E171
Antimony (HCl-soluble)	mg/kg	C101130	< 2		2	E171
Mercury (HCl-soluble)	mg/kg	C101130	< 1,0		1,0	E171
Cadmium (HCl-soluble)	mg/kg	C101130	< 1,0		1,0	E171
Nano Content by number (calc.)	%	FT050100	6		19	E171
Titanium Dioxide	%	S-1008	99,1	98,0	100,5	EP
Identity		C101206	meets spec			USP/EP/JP
Water soluble substances	%	B318-01	0,2		0,5	EP
Arsenic (total)	mg/kg	C101-126	< 1		1	EP
Antimony (total)	mg/kg	C101-126	< 1		2	EP
Barium (total)	mg/kg	C101-126	< 20		20	EP
Iron (total)	mg/kg	C101101C	< 200		200	EP
Lead (total)	mg/kg	C101-126	< 1		5	EP
Appearance of solution		C101204	meets spec			EP
Acidity or alkalinity		C101204	< 1,0		1,0	EP
Titanium Dioxide	%	S-1008	99,1	98,5		JP
Identity		C101206	meets spec			USP/EP/JP
Loss on drying	%	S-1003A	0,1		0,5	JP
Water soluble substances	%	B318-01	0,20		0,25	JP
Arsenic (total)	mg/kg	C101-126	< 10		10	JP
Lead (total)	mg/kg	C101101C	< 60		60	JP
Total Yeast and Moulds Count (TYMC)	cfu/g	R200-06	< 100		100	

Kli / 25

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Germany

Delivered board numbers:
D2FR44/09, D2FR44/10, D2FR44/11, D2FR44/12, D2FR44/13, D2FR44/14, D2FR44/15, D2FR44/16, D2FR44/17, D2FR44/18.

CERTIFICATE OF ANALYSIS	
E-Mail:	Customer_Service_Specialties1@venatorcorp.com Customer_Service_Specialties2@venatorcorp.com Customer_Service_Specialties@venatorcorp.com TioxideUS_Customer_Services@venatorcorp.com
Customer Purchase order no:	212-11901-OP
Sales order no:	631112
Delivery no:	81116763
Customer no:	34567
Product code:	AFDC101_AA
Delivery quantity:	10,000 kg
Batch number:	D2FR440019

AFDC101_1; AFDC101_905; 300000130180644; 6.9.2022; 2.3

Test parameter	Unit	Method	Test value	Lower limit	Upper Limit	Reference
Total Aerobic Microbial Count (TAMC)	cfu/g	R200-01	< 100		100	
Escherichia coli absent in 1g		R200-12	meets spec			
Pseudomonas aeruginosa absent in 1g		R200-12	meets spec			
Staphylococcus aureus absent in 1g		R200-12	meets spec			
Salmonella spp. absent in 10g		R200-12	meets spec			
Candida albicans absent in 1g		R200-12	meets spec			
Bile tol. Gram neg. Bact. absent in 1g		R200-12	meets spec			
Clostridia absent in 1g		R200-12	meets spec			
pH-value		S-1001	7,0	6,5	8,5	

Appearance: white powder, odourless.
The product meets the specifications of USP, EP, JP, FDA (21 CFR 73.575; 73.1575; 73.2575 and 73.3126), EU (E171 in 231/2012/EC), FCC and JECFA on the date of production.
Residual solvents USP < 467 >: No solvents used during manufacture.
No animal derived or GMO material used during manufacture.

Shelf-life: HOMBITAN Titanium Dioxides as inorganic compounds are extremely stable if stored dry at ambient temperatures. Therefore no shelf-life is defined. The only possible change could be a decrease in dispersibility due to potential formation of agglomerates. Depending on the application an adequate dispersion has to be taken care of. We recommend using the product within 3 years after production.

The nano-content of nanoparticles by number is calculated by using the correlation between SEM (Scanning Electron Microscopy) measurements and CBL (Coulter Beilong Untertone) results. Correlation curves can be provided on demand. According to a result of less than 50 % by number the material is not a nanomaterial pursuant to the Commission Recommendation of 18th October 2011 on the definition of nanomaterial, the EU Regulation 2017/45 of April 2017 on Medical Devices, and the French Decree no. 2012-232 of 17th February 2012 on the annual declaration on substances at nanoscale.

The character "<" corresponds to the expression "not more than (nmt)" in the mentioned pharmacopeias.
Test values are based on analyses carried out in the Quality Control Laboratory of Venator Germany GmbH promptly after production with the exception of pathogens. Analyses of pathogens are carried out by the laboratories of Henkel AG & Co. KGaA, Düsseldorf.

The material is certified according to FSSC 22000. FDA Registration No. 12754601774

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Sitz der Gesellschaft: D-47198 Duisburg, Amtsgericht Duisburg HR B 19669
VAT Registration No.: DE 814 031 123

Date of Approval:

06. SEP. 2022

Authorised signature:

[Signature]
Head of Quality Control

The Venator Germany GmbH standard terms and conditions of sale shall apply.