



KRONOS INTERNATIONAL, Inc.
Peschstr. 5, D-51373 Leverkusen
0049 (0) 214 356 0
kronos.leverkusen@kronosww.com

Certificate of Analysis

Titanium Dioxide KRONOS 1171 (E171)

Leverkusen June 30, 2023
Lot No: 0063150
Date of Production: June 15, 2023
Use-by-Date: June 2028
Production Site: KRONOS Canada, Inc, 3390 Boulevard Marie-Victorin,
Varenes, Québec, Canada J3X 1T4
Analysis Laboratory: KRONOS INTERNATIONAL, Inc., Department Research Services,
Leverkusen/Germany

Test Report - 3.1 acc to DIN EN 10204:2005

The Lot, as analyzed, meets the analytical specification of the Pharmacopoeias - Ph. Eur., BP, USP, JP - and also the specification of the Commission Regulation (EU) No. 231/2012 and the FDA regulation (873.373) of the current versions at the time of printing.

The most stringent requirement of the pharmacopoeias mentioned above has been determined as specification limit.

This specific Lot KRONOS 1171 is approved for pharma, food, feed and cosmetic applications and for use in food contact materials.

It is not approved for food and feed in the European Union.
The respective national legislation must be observed.

USP Chapter <467> Residual Solvents

During the production of Titanium Dioxide KRONOS 1171 no solvents are used, so no residual solvents are to be expected in the final products.

Titanium Dioxide KRONOS 1171 is in compliance with "ICH Guideline Q3C (R6) on Impurities: Guideline for Residual Solvents".

Titanium Dioxide KRONOS 1171 is not exposed to any of the class 1, 2, or 3 solvents (organic volatile impurities) addressed in the current US Pharmacopoeia (USP) chapter <467> during manufacturing, handling or storage. Since there is no potential for the above named substances to be present, testing is not performed as prescribed in the current USP Chapter <467>. If tested for residual solvents, Titanium Dioxide KRONOS 1171 would comply with the standards established in the current USP chapter <467>.

Property	Unit	Standard based on	Value	Limits
Identity		DIN EN 13925-3	complies	complying
Assay, Titanium Dioxide (TiO ₂)	% (m)	DIN EN ISO 591-1	99.1	98.0 - 100.5
Assay, Titanium Dioxide (TiO ₂) (calc. to dried substance)	% (m)	DIN EN ISO 591-1	99.2	99.0 - 100.5
Appearance		EU No. 231/2012	white to almost white powder	
Solubility		EU No. 231/2012	meets specification EU No. 231/2012	
Clarity / Color of Solution		Ph. Eur.	complies	complying
Acidity / Alkalinity	ml	Ph. Eur.	< 1.0	<= 1.0
Water Soluble Substances	% (m)	USP	0.20	<= 0.25

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** COPIA VALIDADA **

Alb./Fecha: 0162140960 900001/22.03.2024 Prod.: KRONOS 1171 TITANDIOXID PH SP 20 K Cant.: 1.040 KG
Código Brenntag: 20000010547 Lote Brenntag: 0011610827 Lote Fabricante: 0063150
S/Ref. Pedido: P024-0000266 S/Ref. Artículo:
Extendido para: MANA PHARMA S.L. Ref. Certificado: 906108
Los datos contenidos en esta hoja se facilitan a título informativo únicamente y no eximen al receptor de la necesidad del preceptivo examen/comprobación para su aceptación a la entrega.



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Property	Unit	Standard based on	Value	Limits
Nickel (Ni), total	mg/kg	USP <233>	0.4	info only
Cobalt (Co), total	mg/kg	USP <233>	< 0.1	info only
Copper (Cu), total	mg/kg	USP <233>	< 2.0	info only
Zinc (Zn), total	mg/kg	USP <233>	< 2.0	info only
Chromium (Cr), total	mg/kg	USP <233>	1.8	info only
Selenium (Se), total	mg/kg	USP <233>	< 0.5	info only
Vanadium (V), total	mg/kg	USP <233>	4.9	info only

I.V.
Dr. Thomas Koch
Manager Analytical Intelligence

J.A.
René Müller
Supervisor Instrumental Analytics

Vérifié par: Karlheinz St. Schmid
Date: 2023 07 14

Board of Directors: Dr. Hans-Joachim Lippert, Dr. Hans-Joachim Lippert, Dr. Hans-Joachim Lippert, Dr. Hans-Joachim Lippert, Dr. Hans-Joachim Lippert
Registered with the Federal Patent Office of the German Patent Office (BPA) in Munich, Germany (BPA) (USA) / Leverkusen
US Patent No. 7,111,111 (2003)

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Property	Unit	Standard based on	Value	Limits
Water Soluble Substances	%(m)	EU No. 231/2012	0.36	<= 0.5
Acid (HCl 0.5 mol/l) Soluble Substances	%(m)	USP	0.30	<= 0.5
Loss on Drying (105 °C, 3 h)	%(m)	USP	0.15	<= 0.5
Loss on Ignition (800 °C)	%(m)	USP	0.04	<= 0.5
Lead (Pb), HCl soluble	mg/kg	FDA 573.575	0.3	<= 10
Arsenic (As), HCl soluble	mg/kg	FDA 573.575	< 0.1	<= 1
Antimony (Sb), HCl soluble	mg/kg	FDA 573.575	< 0.1	<= 2
Barium (Ba), total	mg/kg	USP <233>	2.5	<= 20
Arsenic (As), total	mg/kg	USP <233>	< 0.1	<= 1
Iron (Fe), total	mg/kg	USP <233>	10.6	<= 200
Antimony (Sb), total	mg/kg	USP <233>	< 0.1	<= 2
Lead (Pb), total	mg/kg	USP <233>	0.7	<= 5
Mercury (Hg), total	mg/kg	FCC	< 0.1	<= 1
Cadmium (Cd), HCl soluble	mg/kg	EU No. 231/2012	< 0.1	<= 1
Mercury (Hg), HCl soluble	mg/kg	EU No. 231/2012	< 0.1	<= 1
Aluminium Oxide and/or Silicon Dioxide	%(m)	DIN 51418	0.01	<= 2
PLV Brightness		DIN 53163	98.9	98.4 - 99.4
PLV Tone b*		DIN 53163	0.27	0.00 - 1.00
pH Value in 10% Suspension		ISO 787-9	7.3	7.0 - 8.5
Cadmium (Cd), total	mg/kg	USP <233>	< 0.1	Info only

Board of Directors/Verwaltungsrat: Jochen M. Bunn, Rainer Grottel, Tim C. Heiser, Ulrich Kasper
Registrierungsnummer: HRB 160118, Amtsgericht: Schornheim, Kreis: Bad. Nauh., Leverkusen
USt-IdNr.: DE 251460137

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