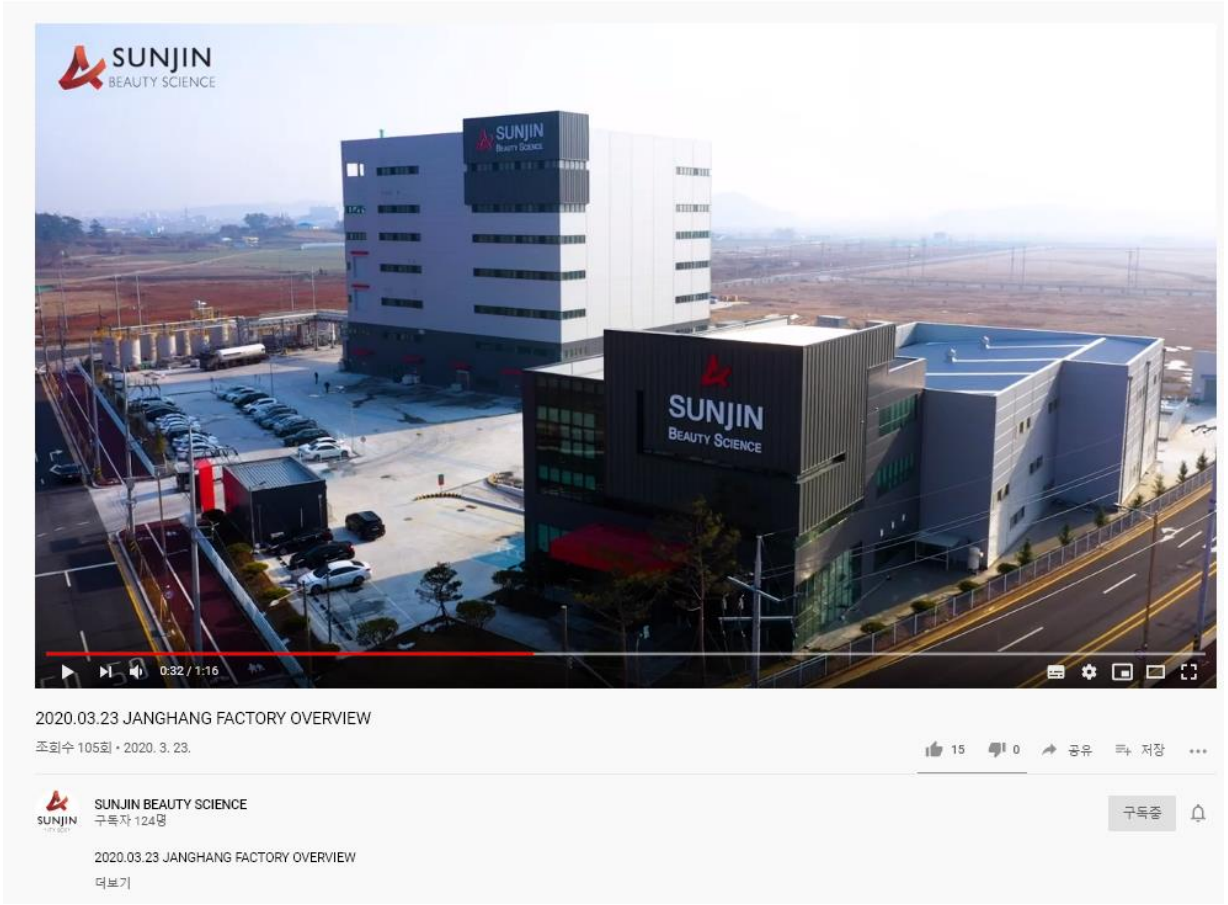
Titanium Dioxide

SUNJIN BEAUTY SCIENCE
AUG 2020
Ver3.0

SUNJIN Youtube



https://www.youtube.com/watch?v=BcgMqJO_1dU&t=7s

Please subscribe SUNJIN BEAUTY SCIENCE

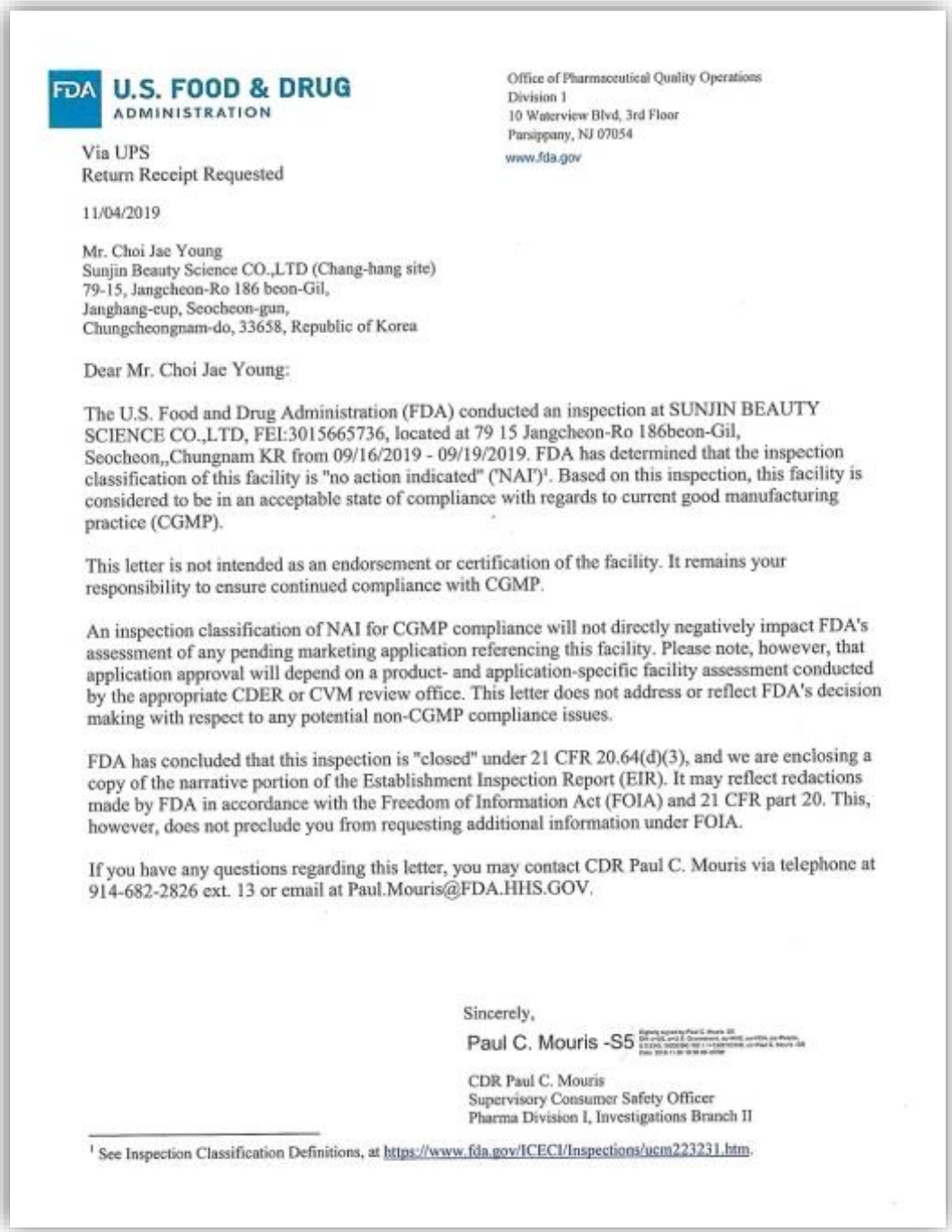
FDA Inspection

Inspection Site:
Janghang Factory

Inspection Date:
09/16/2019 – 09/19/2019

Inspection Result:
"No action indicated" ('NAI').

Based on this inspection, this facility is considered to be **in an acceptable state** of compliance with regards to current good manufacturing practice (**CGMP**).



FDA U.S. FOOD & DRUG ADMINISTRATION

Office of Pharmaceutical Quality Operations
Division 1
10 Waterview Blvd, 3rd Floor
Parsippany, NJ 07054
www.fda.gov

Via UPS
Return Receipt Requested

11/04/2019

Mr. Choi Jae Young
Sunjin Beauty Science CO.,LTD (Chang-hang site)
79-15, Jangcheon-Ro 186 beon-Gil,
Janghang-eup, Seocheon-gun,
Chungcheongnam-do, 33658, Republic of Korea

Dear Mr. Choi Jae Young:

The U.S. Food and Drug Administration (FDA) conducted an inspection at SUNJIN BEAUTY SCIENCE CO.,LTD, FEI:3015665736, located at 79 15 Jangcheon-Ro 186beon-Gil, Seocheon,,Chungnam KR from 09/16/2019 - 09/19/2019. FDA has determined that the inspection classification of this facility is "no action indicated" ('NAI')[1]. Based on this inspection, this facility is considered to be in an acceptable state of compliance with regards to current good manufacturing practice (CGMP).

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of NAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by the appropriate CDER or CVM review office. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA in accordance with the Freedom of Information Act (FOIA) and 21 CFR part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact CDR Paul C. Mouris via telephone at 914-682-2826 ext. 13 or email at Paul.Mouris@FDA.HHS.GOV.

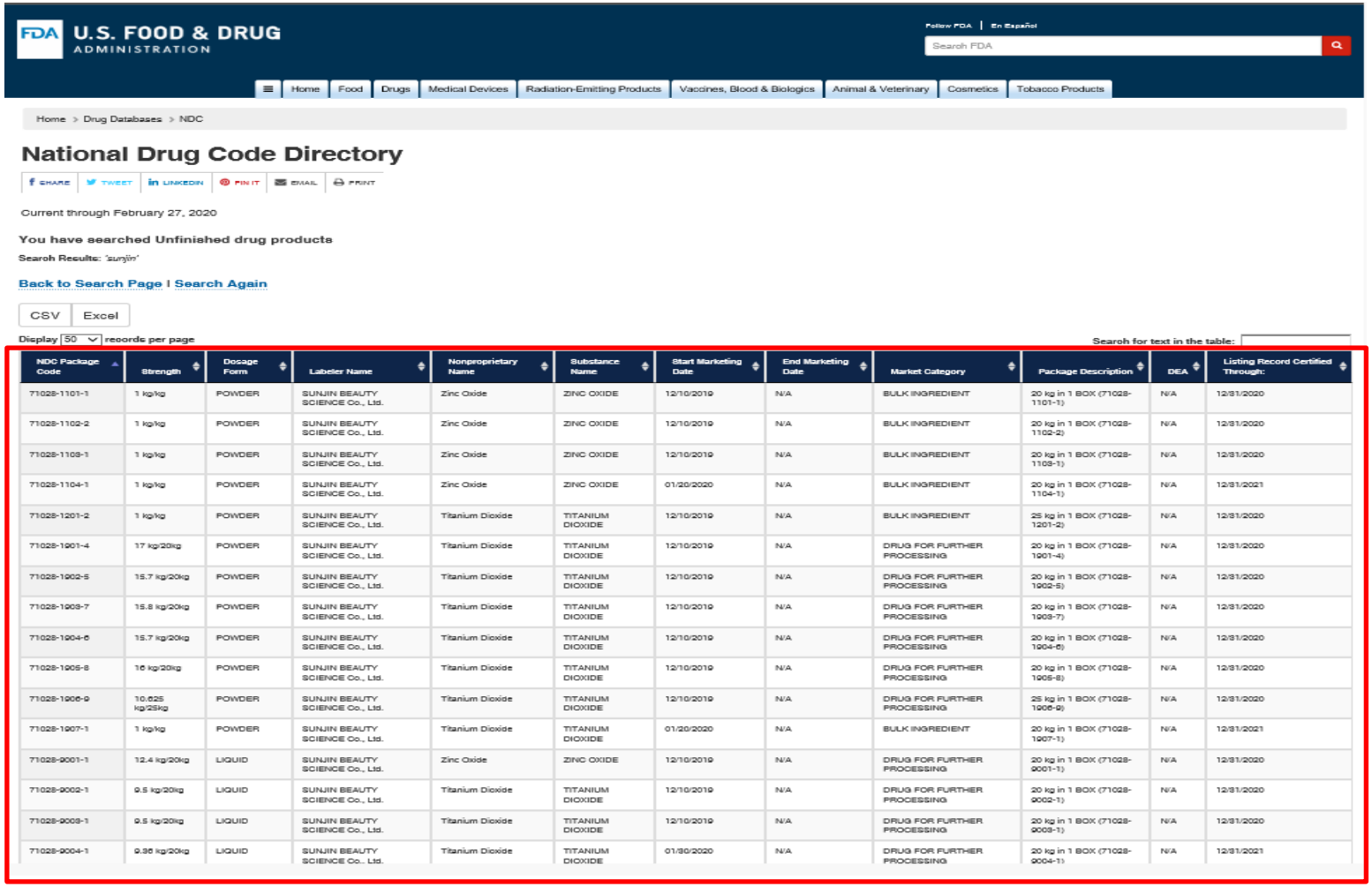
Sincerely,

Paul C. Mouris -S5

CDR Paul C. Mouris
Supervisory Consumer Safety Officer
Pharma Division I, Investigations Branch II

[1] See Inspection Classification Definitions, at https://www.fda.gov/ICECI/Inspections/ucm223231.htm.

NDC: National Drug Code



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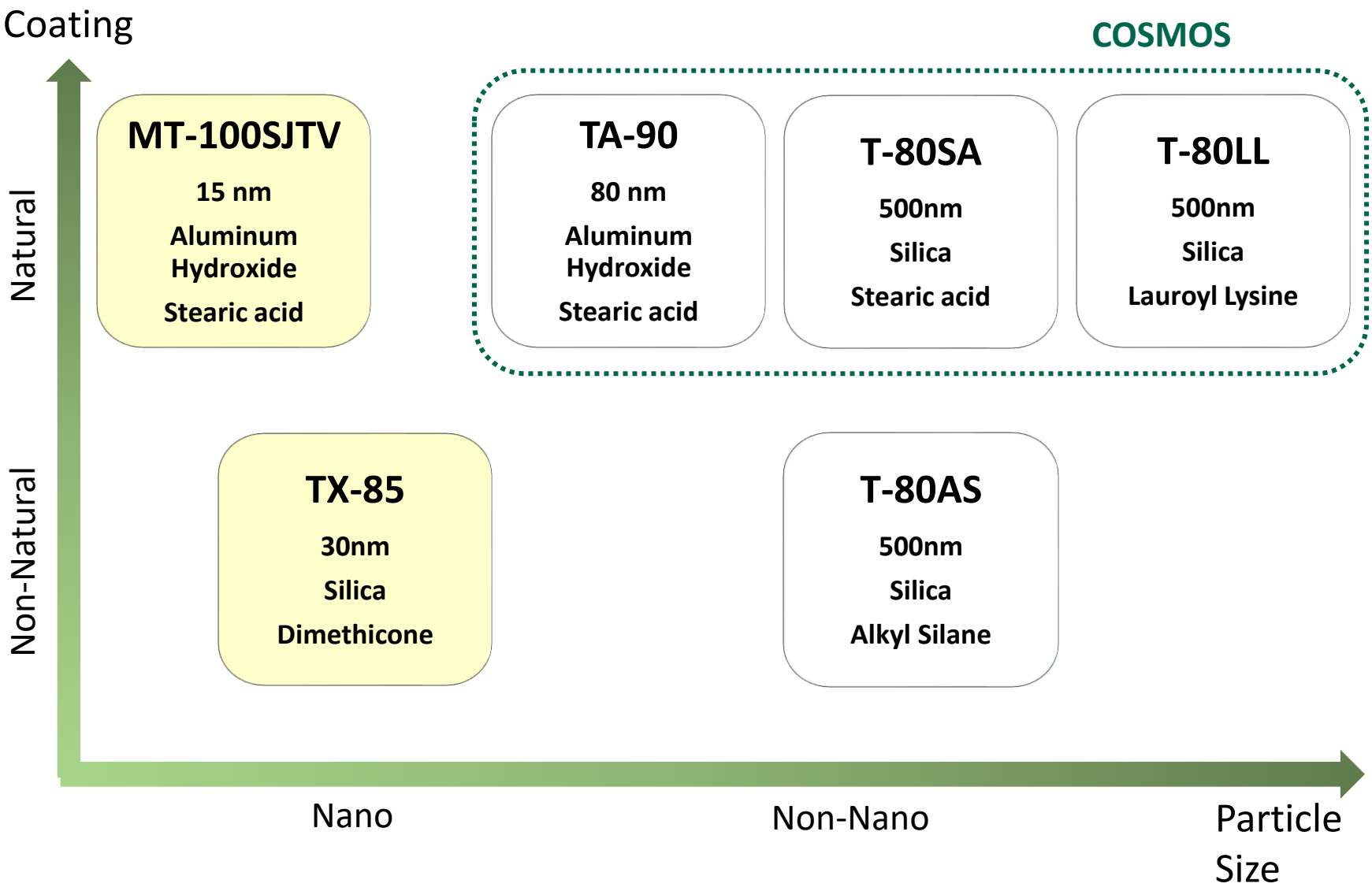
NDC Package Code	Strength	Dosage Form	Labeler Name	Nonproprietary Name	Substance Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	DEA	Listing Record Certified Through:
71028-1101-1	1 kg/kg	POWDER	SUNJIN BEAUTY SCIENCE Co., Ltd.	Zinc Oxide	ZINC OXIDE	12/10/2019	N/A	BULK INGREDIENT	20 kg in 1 BOX (71028-1101-1)	N/A	12/31/2020
71028-1102-2	1 kg/kg	POWDER	SUNJIN BEAUTY SCIENCE Co., Ltd.	Zinc Oxide	ZINC OXIDE	12/10/2019	N/A	BULK INGREDIENT	20 kg in 1 BOX (71028-1102-2)	N/A	12/31/2020
71028-1103-1	1 kg/kg	POWDER	SUNJIN BEAUTY SCIENCE Co., Ltd.	Zinc Oxide	ZINC OXIDE	12/10/2019	N/A	BULK INGREDIENT	20 kg in 1 BOX (71028-1103-1)	N/A	12/31/2020
71028-1104-1	1 kg/kg	POWDER	SUNJIN BEAUTY SCIENCE Co., Ltd.	Zinc Oxide	ZINC OXIDE	01/20/2020	N/A	BULK INGREDIENT	20 kg in 1 BOX (71028-1104-1)	N/A	12/31/2021
71028-1201-2	1 kg/kg	POWDER	SUNJIN BEAUTY SCIENCE Co., Ltd.	Titanium Dioxide	TITANIUM DIOXIDE	12/10/2019	N/A	BULK INGREDIENT	25 kg in 1 BOX (71028-1201-2)	N/A	12/31/2020
71028-1901-4	17 kg/20kg	POWDER	SUNJIN BEAUTY SCIENCE Co., Ltd.	Titanium Dioxide	TITANIUM DIOXIDE	12/10/2019	N/A	DRUG FOR FURTHER PROCESSING	20 kg in 1 BOX (71028-1901-4)	N/A	12/31/2020
71028-1902-5	15.7 kg/20kg	POWDER	SUNJIN BEAUTY SCIENCE Co., Ltd.	Titanium Dioxide	TITANIUM DIOXIDE	12/10/2019	N/A	DRUG FOR FURTHER PROCESSING	20 kg in 1 BOX (71028-1902-5)	N/A	12/31/2020
71028-1903-7	15.8 kg/20kg	POWDER	SUNJIN BEAUTY SCIENCE Co., Ltd.	Titanium Dioxide	TITANIUM DIOXIDE	12/10/2019	N/A	DRUG FOR FURTHER PROCESSING	20 kg in 1 BOX (71028-1903-7)	N/A	12/31/2020
71028-1904-6	15.7 kg/20kg	POWDER	SUNJIN BEAUTY SCIENCE Co., Ltd.	Titanium Dioxide	TITANIUM DIOXIDE	12/10/2019	N/A	DRUG FOR FURTHER PROCESSING	20 kg in 1 BOX (71028-1904-6)	N/A	12/31/2020
71028-1905-8	16 kg/20kg	POWDER	SUNJIN BEAUTY SCIENCE Co., Ltd.	Titanium Dioxide	TITANIUM DIOXIDE	12/10/2019	N/A	DRUG FOR FURTHER PROCESSING	20 kg in 1 BOX (71028-1905-8)	N/A	12/31/2020
71028-1906-9	10.625 kg/25kg	POWDER	SUNJIN BEAUTY SCIENCE Co., Ltd.	Titanium Dioxide	TITANIUM DIOXIDE	12/10/2019	N/A	DRUG FOR FURTHER PROCESSING	25 kg in 1 BOX (71028-1906-9)	N/A	12/31/2020
71028-1907-1	1 kg/kg	POWDER	SUNJIN BEAUTY SCIENCE Co., Ltd.	Titanium Dioxide	TITANIUM DIOXIDE	01/20/2020	N/A	BULK INGREDIENT	20 kg in 1 BOX (71028-1907-1)	N/A	12/31/2021
71028-9001-1	12.4 kg/20kg	LIQUID	SUNJIN BEAUTY SCIENCE Co., Ltd.	Zinc Oxide	ZINC OXIDE	12/10/2019	N/A	DRUG FOR FURTHER PROCESSING	20 kg in 1 BOX (71028-9001-1)	N/A	12/31/2020
71028-9002-1	9.5 kg/20kg	LIQUID	SUNJIN BEAUTY SCIENCE Co., Ltd.	Titanium Dioxide	TITANIUM DIOXIDE	12/10/2019	N/A	DRUG FOR FURTHER PROCESSING	20 kg in 1 BOX (71028-9002-1)	N/A	12/31/2020
71028-9003-1	9.5 kg/20kg	LIQUID	SUNJIN BEAUTY SCIENCE Co., Ltd.	Titanium Dioxide	TITANIUM DIOXIDE	12/10/2019	N/A	DRUG FOR FURTHER PROCESSING	20 kg in 1 BOX (71028-9003-1)	N/A	12/31/2020
71028-9004-1	9.96 kg/20kg	LIQUID	SUNJIN BEAUTY SCIENCE Co., Ltd.	Titanium Dioxide	TITANIUM DIOXIDE	01/30/2020	N/A	DRUG FOR FURTHER PROCESSING	20 kg in 1 BOX (71028-9004-1)	N/A	12/31/2021

https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm

TiO2 Overview

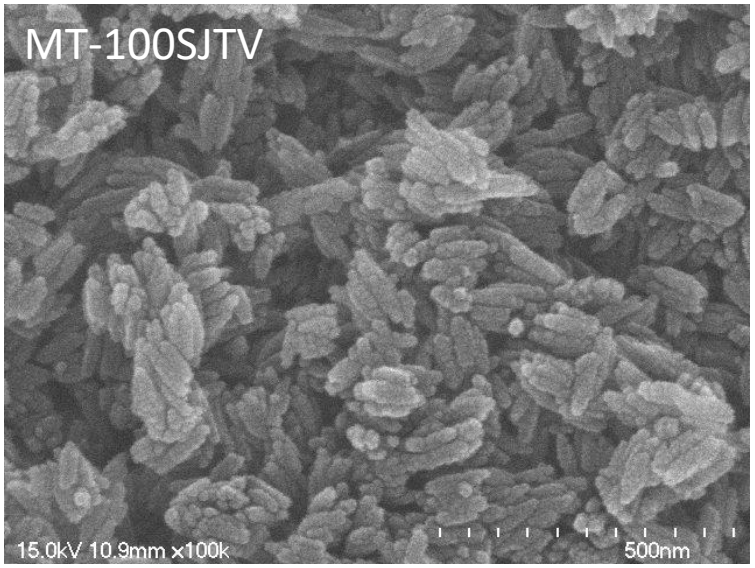


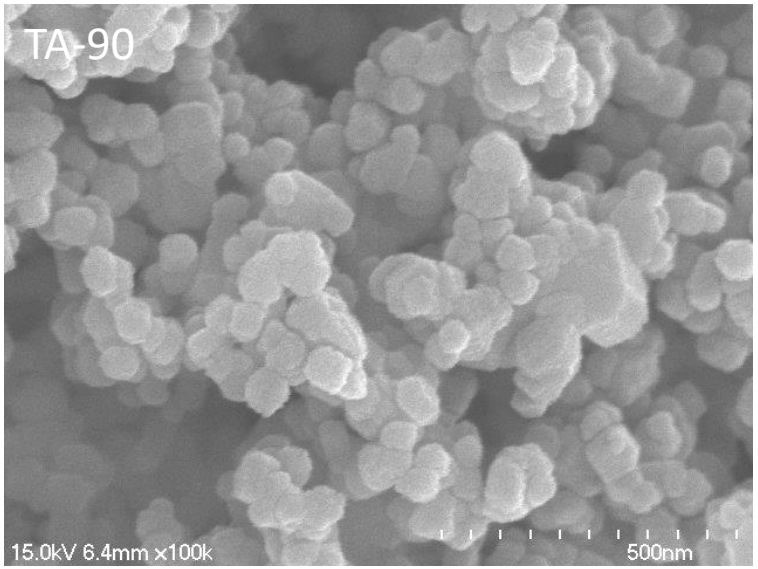
TiO2 Overview

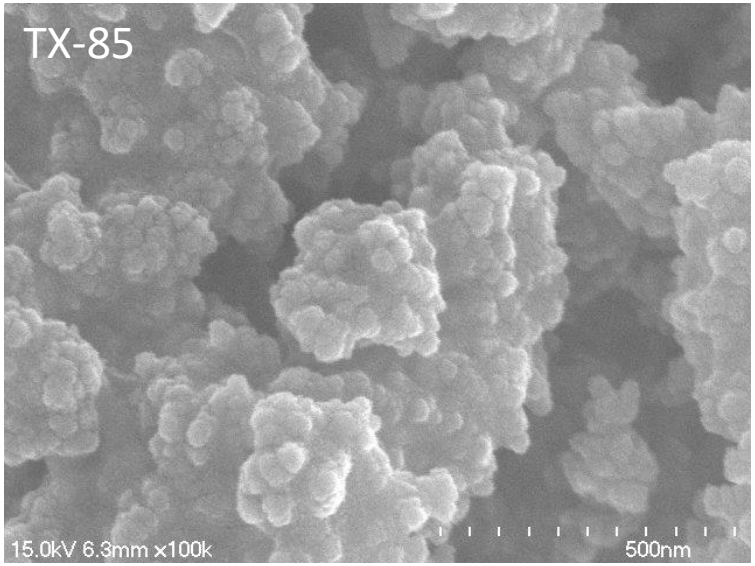
	MT-100SJTV	TX-85	TA-90	T-80SA	T-80LL	T-80AS
TiO2 Purity %	82%	80%	80%	80%	80%	80%
TiO2 Coating	Aluminum Hydroxide & Stearic Acid	Silica & Dimethicone	Aluminum Hydroxide & Stearic Acid	Silica & Stearic Acid	Silica & Lauroyl Lysine	Silica & Triethoxycaprylylsilane
Particle size	15nm	30nm	80nm	500nm	500nm	500nm
Shape (Morphology)	Needle	Round	Round	Round	Round	Round
Transparency by White index	46.47	48.81	60.91	-	-	67.73
Remarks	Transparent	SCCS Opinion Compliat Nano TiO2	COSMOS RSPO	Non-Nano COSMOS RSPO	Non-Nano COSMOS RSPO	Non-Nano

TiO2 Overview

by SEM







TiO2 Overview

by White Index

Tested W/O fomula

SJF-1921-W/O COSMOS
SUNCARE SPF30 PA+++_ver1.0

The Higher White index, the less transparent

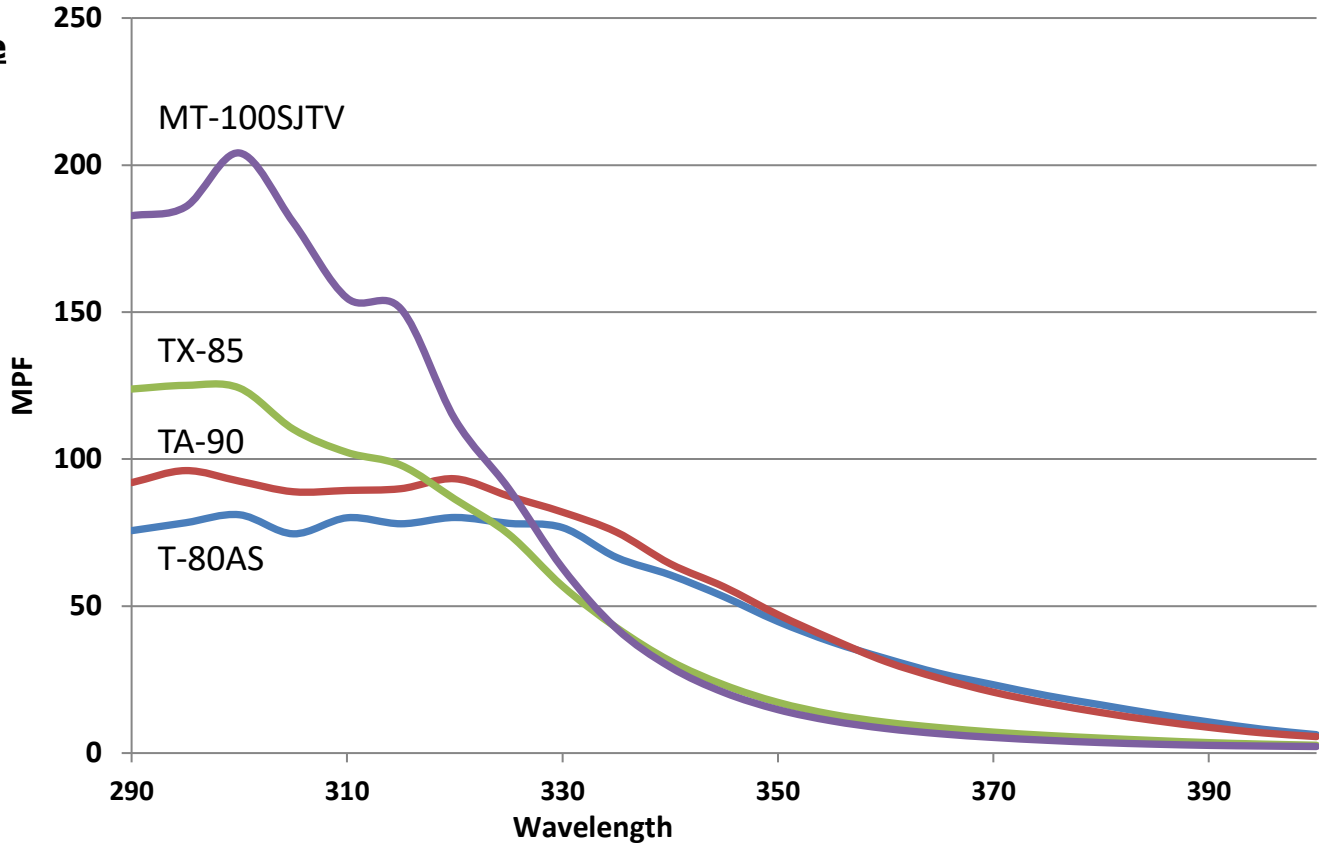
NIPPON DENSHOKU
COLOR METER ZE 2000

TiO2 Overview

by In-vitro

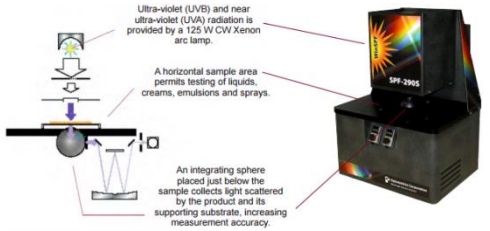
Tested Titanium Oxide

#1
Company : SUNJIN
Product : MT-100SJTV
#2
Company : SUNJIN
Product : TX-85
#3
Company : SUNJIN
Product : TA-90
#4
Company : SUNJIN
Product : T-80AS



Tested W/O fomula

SJF-1921-W/O COSMOS
SUNCARE SPF30 PA+++_ver1.0



TiO2 Overview

by In-vivo

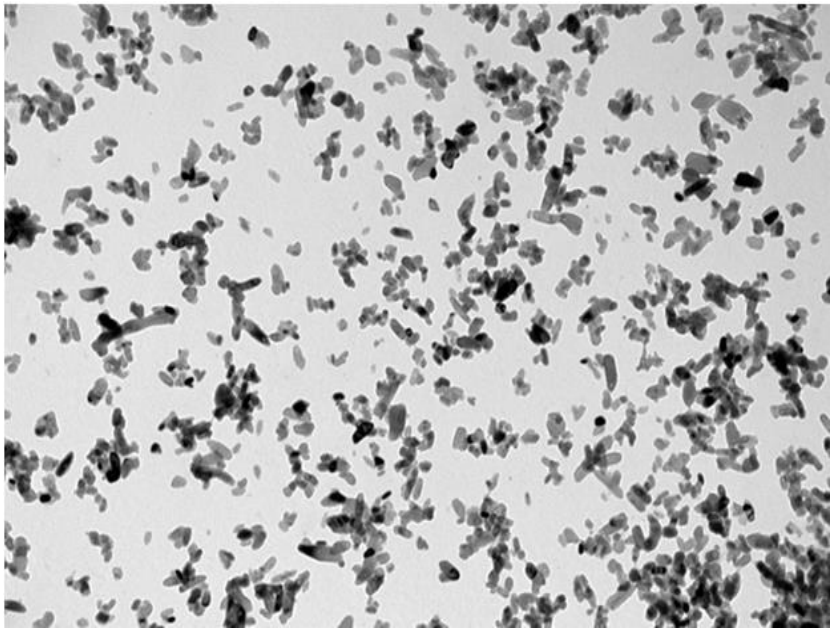
Test Result	MT-100SJTV	TX-85	TA-90	T-80AS
in vivo SPF	40	43.2	37.04	37.04
Determine				
in vivo PA	8	8	9.19	9.19
Determine				

Tested W/O fomula

SJF-1921-W/O COSMOS
SUNCARE SPF30 PA+++_ver1.0

SPF Testing 601 V2.5 Multiport UV Solar Simulator

TX-85 Series



TX-85

TiO2	85%
Silica	10%
Dimethicone	5%

Particle Size
30 nm

SCCS Nano TiO2

TX-85AQ

TiO2	90%
Silica	10%

Particle Size
30 nm

SCCS Nano TiO2

*SCCS: Scientific Committee on Consumer Safety
** http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_136.pdf

SCCS* conformity summary for TiO2

- Purity >99%, Anatase <5%
- Median primary particle size 30~100nm by number based size distribution
- Aspect ratio <4.5
- Volume specific surface area <460m^2/cm^3
- Photo-stable
- Approved coating ingredients**

Inorganic	Organic
Silica	Aluminium stearate
Alumina	Stearate
Hydrated silica	Trimethoxycaprylylsilane
Aluminium hydroxide	Glycerin
	Stearic acid
	Dimethicone
	Dimethicone/methicone copolymer
	Simethicone

* http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_136.pdf
** page 8, Table 1

Dispersibility for TX-85

Tested TiO_2

#1
Company "T"
Product "M"
TiO_2, Alumina, Stearic Acid

#2
Company "S"
Product "M"
TiO_2, Silica, Methicone

#3
Company "D"
Product "P"
TiO_2, Silica, Dimethicone

#4
Company "M"
Product "T"
TiO_2, Silica, Cetyl Phosphate

#5
Company: SUNJIN
Product: TX-85
TiO_2, Silica, Dimethicone

Test condition
Powder 40% ,
Different oil solution 90%

Re-Dispersibility for TX-85

Tested TiO_2

#1
Company "T"
Product "M"
TiO_2, Alumina, Stearic Acid

#2
Company "S"
Product "M"
TiO_2, Silica, Methicone

#3
Company "D"
Product "P"
TiO_2, Silica, Dimethicone

#4
Company "M"
Product "T"
TiO_2, Silica, Cetyl Phosphate

#5
Company: SUNJIN
Product: TX-85
TiO_2, Silica, Dimethicone

Test condition
Powder 1g , Cyclomethicone (D5) 30g
2 Days Later, Upside down test

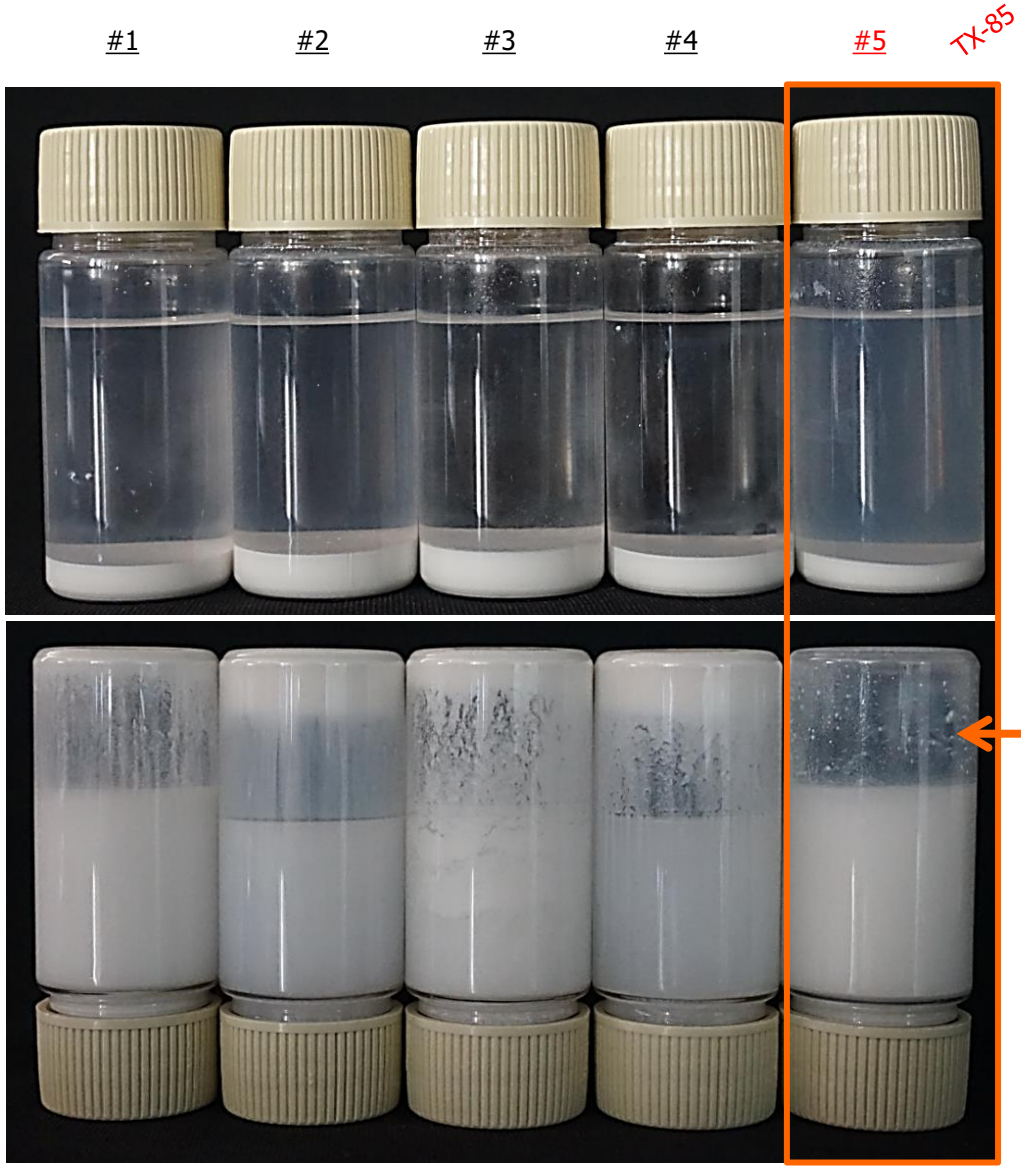


Photo-stability for TX-85

Tested TiO_2

#1
Company "T"
Product "M"
TiO_2, Alumina, Stearic Acid

#2
Company "S"
Product "M"
TiO_2, Silica, Methicone

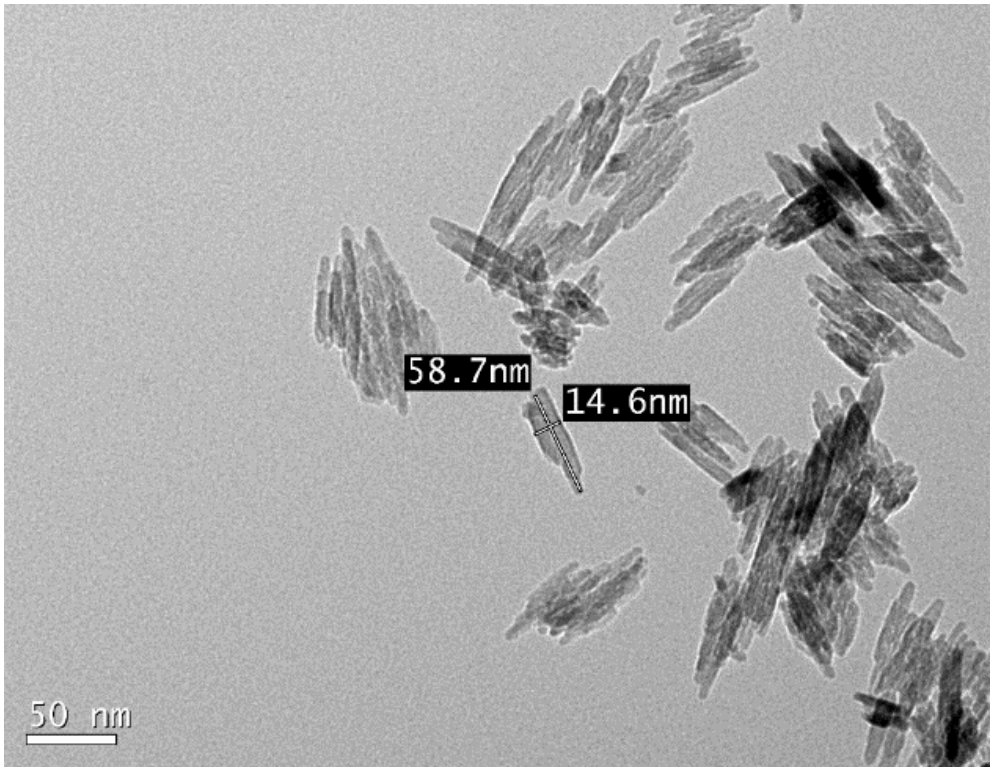
#3
Company "D"
Product "P"
TiO_2, Silica, Dimethicone

#4
Company "M"
Product "T"
TiO_2, Silica, Cetyl Phosphate

#5
Company: SUNJIN
Product: TX-85
TiO_2, Silica, Dimethicone

Test condition
Powder 10% ,Ascorbyl palmitate 2g,
Caprylic/capric triglycerides 88g
After 2hrs

MT-100SJTV



MT-100SJTV

TiO2	82%
Al(OH)3	13%
Stearic Acid	5%

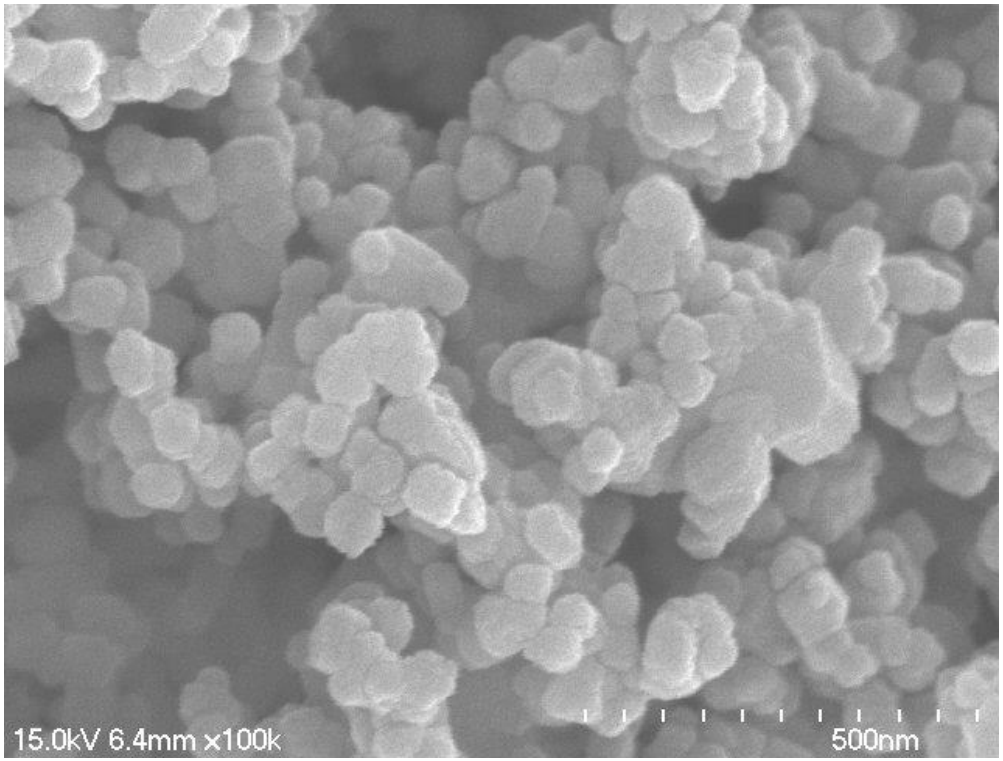
Particle Size
15 nm

Needle Shape

MT-100SJTV Overview

	MT-100SJTV	Product “M”	Test Method
COMPANY	Sunjin	Japan “T”	
Lot No.		3240547	
TiO2 purity (%)		78~88	By Catalog
Surface Treatment	Aluminum Hydroxide 10% Stearic Acid 5%	Aluminum Hydroxide 10% Stearic Acid 5%	
TiO2 purity (%)	83.45	77.09	ICP Analysis by Sunjin
TiO2 purity (%)	TiO2 - 92.801 Al2O3 – 6.278	TiO2 - 93.50 Al2O3 - 5.013	XRF Analysis by Sunjin
Loss on drying (%)	1.38	3.57	130 ºC 30m
Loss on ignition (%)	9.78	14.21	600 ºC 2h
Particle Size (µm)	2.037	2.728	DLS (Malvern)
Tap density (g/ml)	0.325	0.435	-
Surface Area (m2/g)	97.533	58.995	BET
Oil absorption (ml/gm)	0.85	0.8	-

TA-90



TA-90

TiO2	90%
Al(OH)3	5%
Stearic Acid	5%

Particle Size
80 nm

SCCS Nano TiO2

*SCCS: Scientific Committee on Consumer Safety
** http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_136.pdf

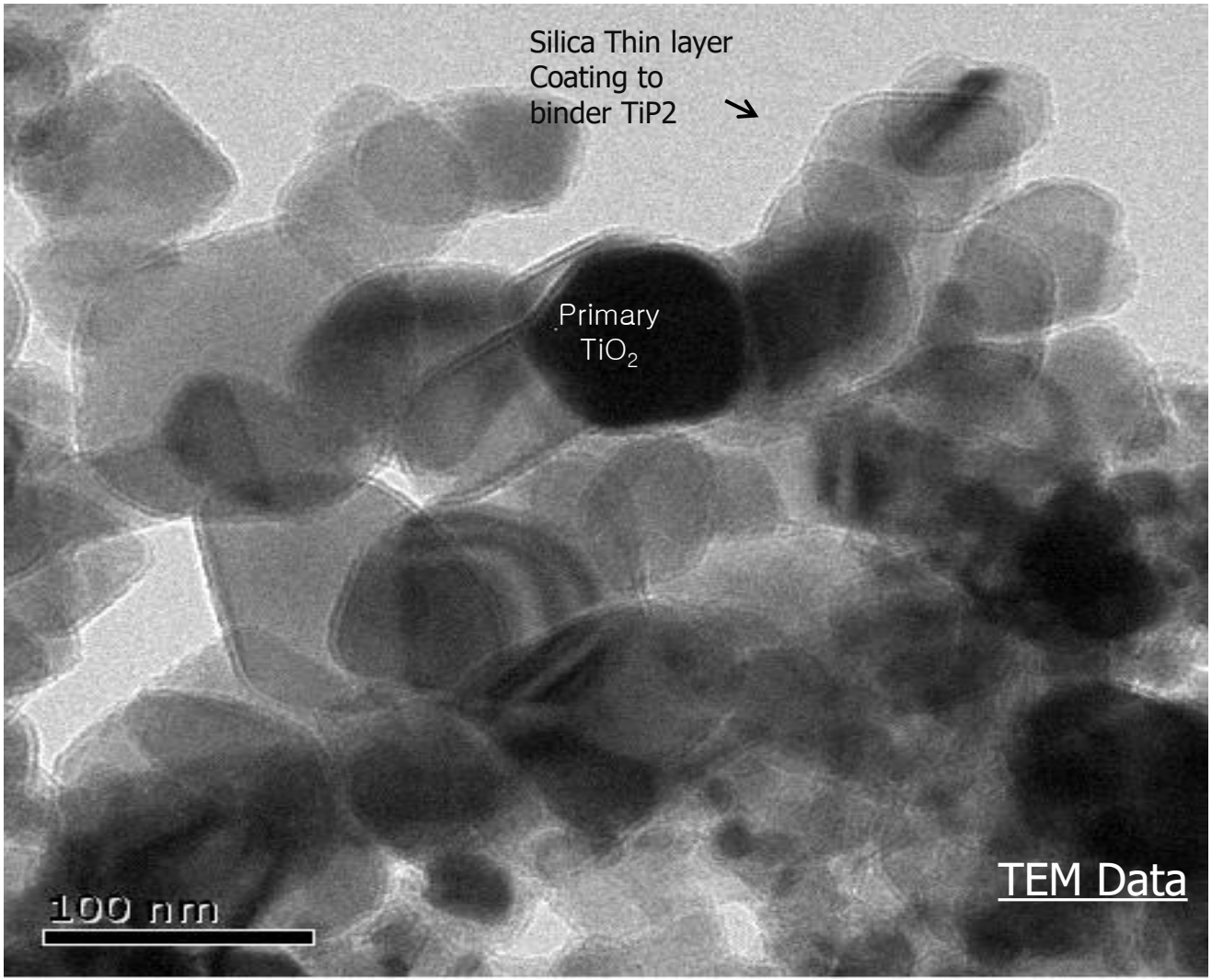
TA-90 @ Air Cushion BB formula

Part	Ingredient	#1	#2
A	Japan "X"	14.2	-
	TA-90	-	14.2
	IOY AS	1.3	1.3
	IOR AS	0.4	0.4
	IOB AS	0.2	0.2
	SUNTALC-AS	1.7	1.7
	DC345	7	7
B	ABIL EM90	3	3
	Cetiol CC	4	4
	Benton 38VCG	0.2	0.2
	Parsol MCX	5	5
	10cs	3	3
	ININ	5.5	5.5
	DC345	3	3
C	KSG16	3	3
D	D.I Water	40.5	40.5
	1,3 BG	7	7
	NaCl	1	1

SPF	42.86	50.01
PA	8.00	8.00

Coverage Comparison

T-80 series

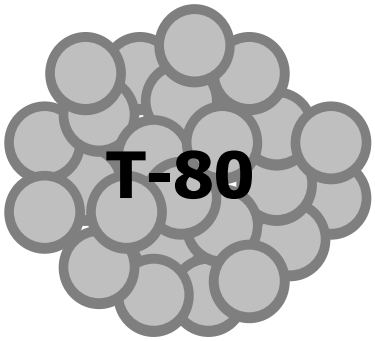


T-80

TiO2	84%
SiO2	16%

Particle Size
500 nm

Non Nano TiO2



Non nano

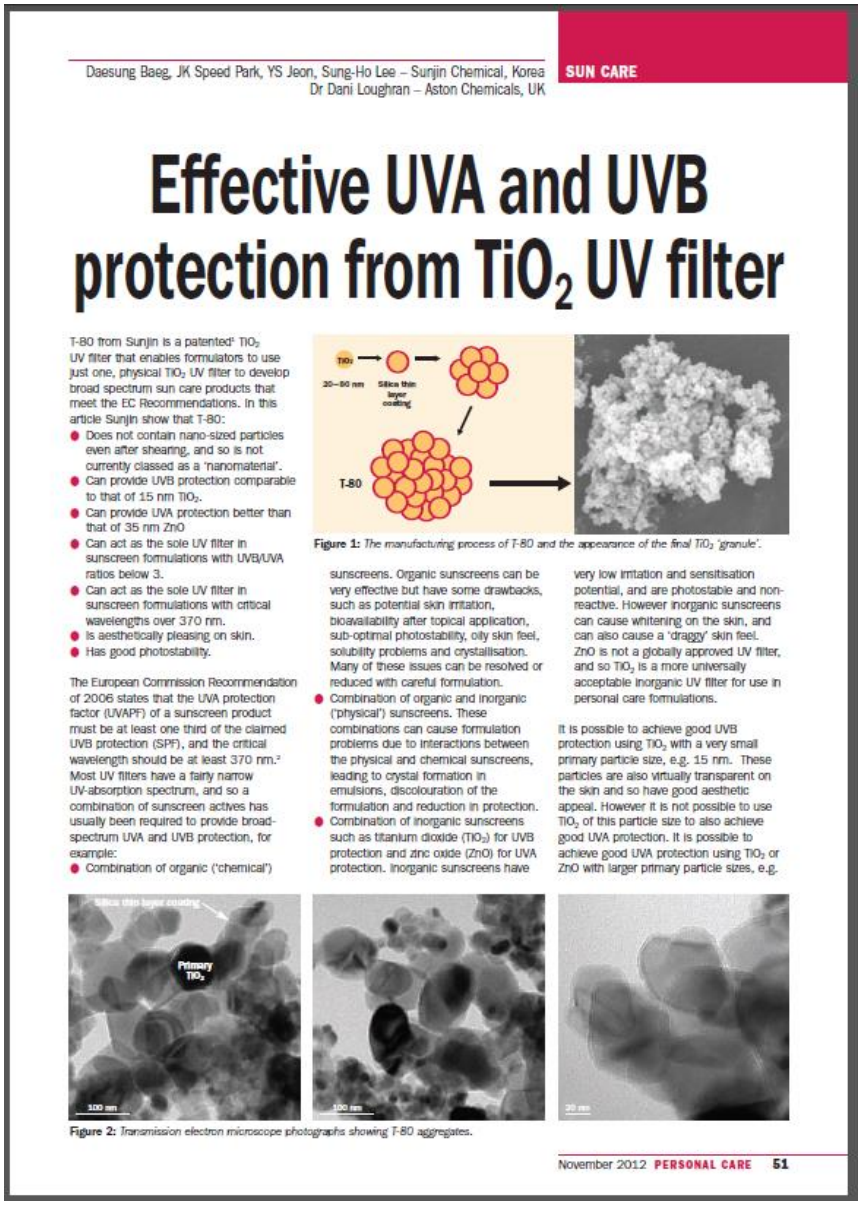
PERSONAL CARE

Nov. 2012

Released in 2012.

Published in 'Personal Care Magazine' in Nov. 2012

Sales of T-80 is spiking worldwide in 2013



Daesung Baeg, JK Speed Park, YS Jeon, Sung-Ho Lee – Sunjin Chemical, Korea
Dr Dani Loughran – Aston Chemicals, UK

Effective UVA and UVB protection from TiO_2 UV filter

T-80 from Sunjin is a patented[1] TiO_2 UV filter that enables formulators to use just one, physical TiO_2 UV filter to develop broad spectrum sun care products that meet the EC Recommendations. In this article Sunjin show that T-80:

- Does not contain nano-sized particles even after shearing, and so is not currently classed as a 'nanomaterial'.
- Can provide UVB protection comparable to that of 15 nm TiO_2.
- Can provide UVA protection better than that of 35 nm ZnO
- Can act as the sole UV filter in sunscreen formulations with UVB/UVA ratios below 3.
- Can act as the sole UV filter in sunscreen formulations with critical wavelengths over 370 nm.
- Is aesthetically pleasing on skin.
- Has good photostability.

The European Commission Recommendation of 2006 states that the UVA protection factor (UVAPF) of a sunscreen product must be at least one third of the claimed UVB protection (SPF), and the critical wavelength should be at least 370 nm.[2] Most UV filters have a fairly narrow UV-absorption spectrum, and so a combination of sunscreen actives has usually been required to provide broad-spectrum UVA and UVB protection, for example:

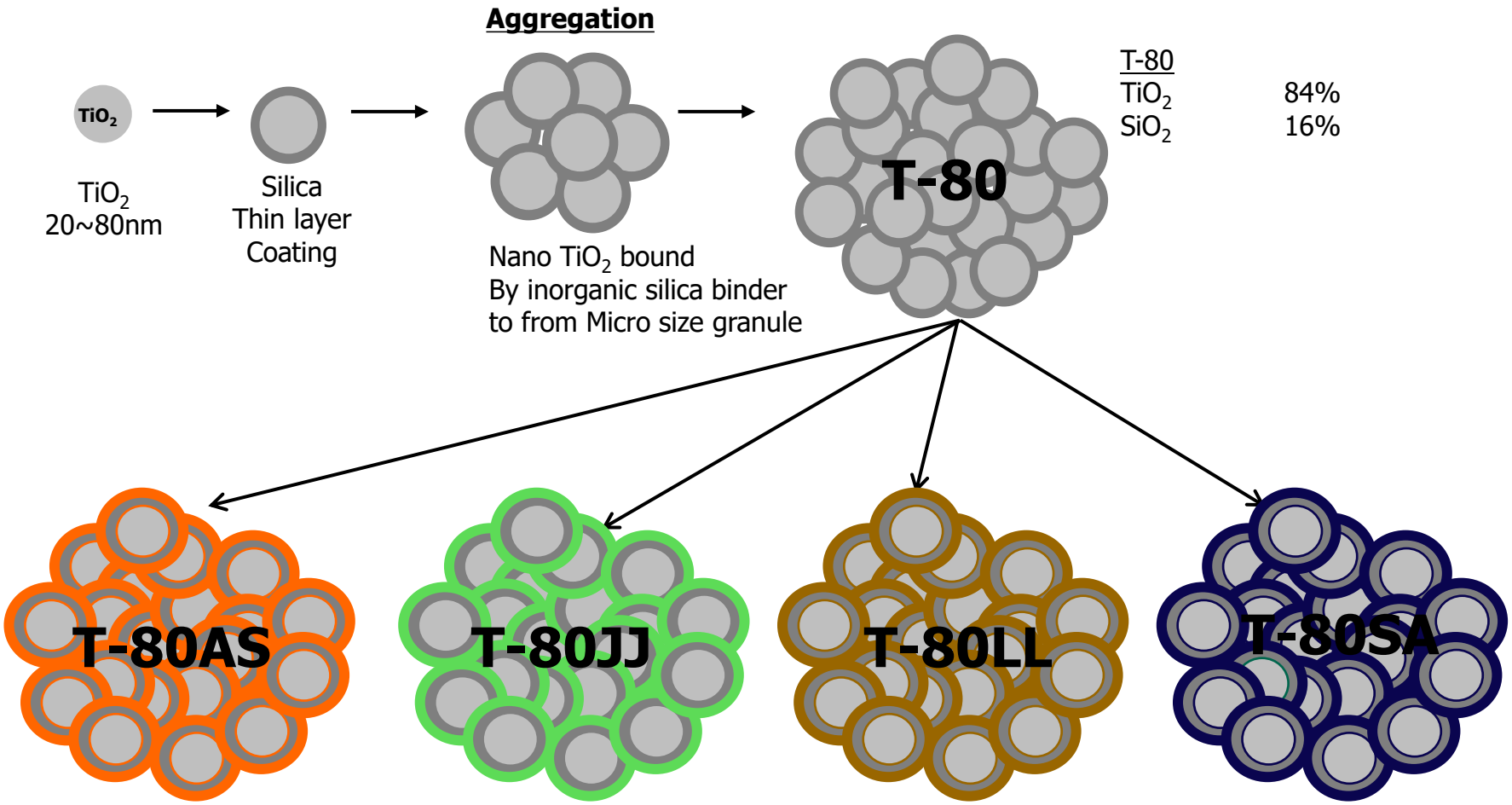
- Combination of organic ('chemical') sunscreens. Organic sunscreens can be very effective but have some drawbacks, such as potential skin irritation, bioavailability after topical application, sub-optimal photostability, oily skin feel, solubility problems and crystallisation. Many of these issues can be resolved or reduced with careful formulation.
- Combination of organic and inorganic ('physical') sunscreens. These combinations can cause formulation problems due to interactions between the physical and chemical sunscreens, leading to crystal formation in emulsions, discolouration of the formulation and reduction in protection.
- Combination of inorganic sunscreens such as titanium dioxide (TiO_2) for UVB protection and zinc oxide (ZnO) for UVA protection. Inorganic sunscreens have very low irritation and sensitisation potential, and are photostable and non-reactive. However inorganic sunscreens can cause whitening on the skin, and can also cause a 'draggy' skin feel. ZnO is not a globally approved UV filter, and so TiO_2 is a more universally acceptable inorganic UV filter for use in personal care formulations.

Figure 1: *The manufacturing process of T-80 and the appearance of the final TiO_2 'granule'.*

It is possible to achieve good UVB protection using TiO_2 with a very small primary particle size, e.g. 15 nm. These particles are also virtually transparent on the skin and so have good aesthetic appeal. However it is not possible to use TiO_2 of this particle size to also achieve good UVA protection. It is possible to achieve good UVA protection using TiO_2 or ZnO with larger primary particle sizes, e.g.

Figure 2: *Transmission electron microscope photographs showing T-80 aggregates.*

T-80 series, Non Nano TiO2



T-80AS
TiO_2 80%
SiO_2 15%
Alkyl Silane 5%

T-80JJ
TiO_2 80%
SiO_2 12%
Jojoba Esters 8%

T-80LL
TiO_2 80%
SiO_2 12%
Lauroyl Lysine 8%

T-80SA
TiO_2 80%
SiO_2 12%
Stearic Acid 8%

% Table of T-80 series for SPF

Category	Labelled sun protection factor	Measured sun protection factor	% of T-80 series needed
Low protection	6	6 – 9.9	**2.0**
	10	10 – 14.9	**3.5**
Medium protection	15	15 – 19.9	**5.5**
	20	20 – 24.9	**7.6**
	25	25 – 29.9	**9.9**
High protection	30	30 – 49.9	**12.4**
	50	50 – 59.9	**25.0**