

Zinc Oxide

SUNJIN BEAUTY SCIENCE

AUG. 2020

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2020.03.23 JANGHANG FACTORY OVERVIEW
조회수 105회 · 2020. 3. 23.

15 0 공유 저장 ...

SUNJIN
BEAUTY SCIENCE
구독자 124명

2020.03.23 JANGHANG FACTORY OVERVIEW
더보기

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

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FDA Inspection



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/icm223231.htm>.

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**).

NDC: National Drug Code

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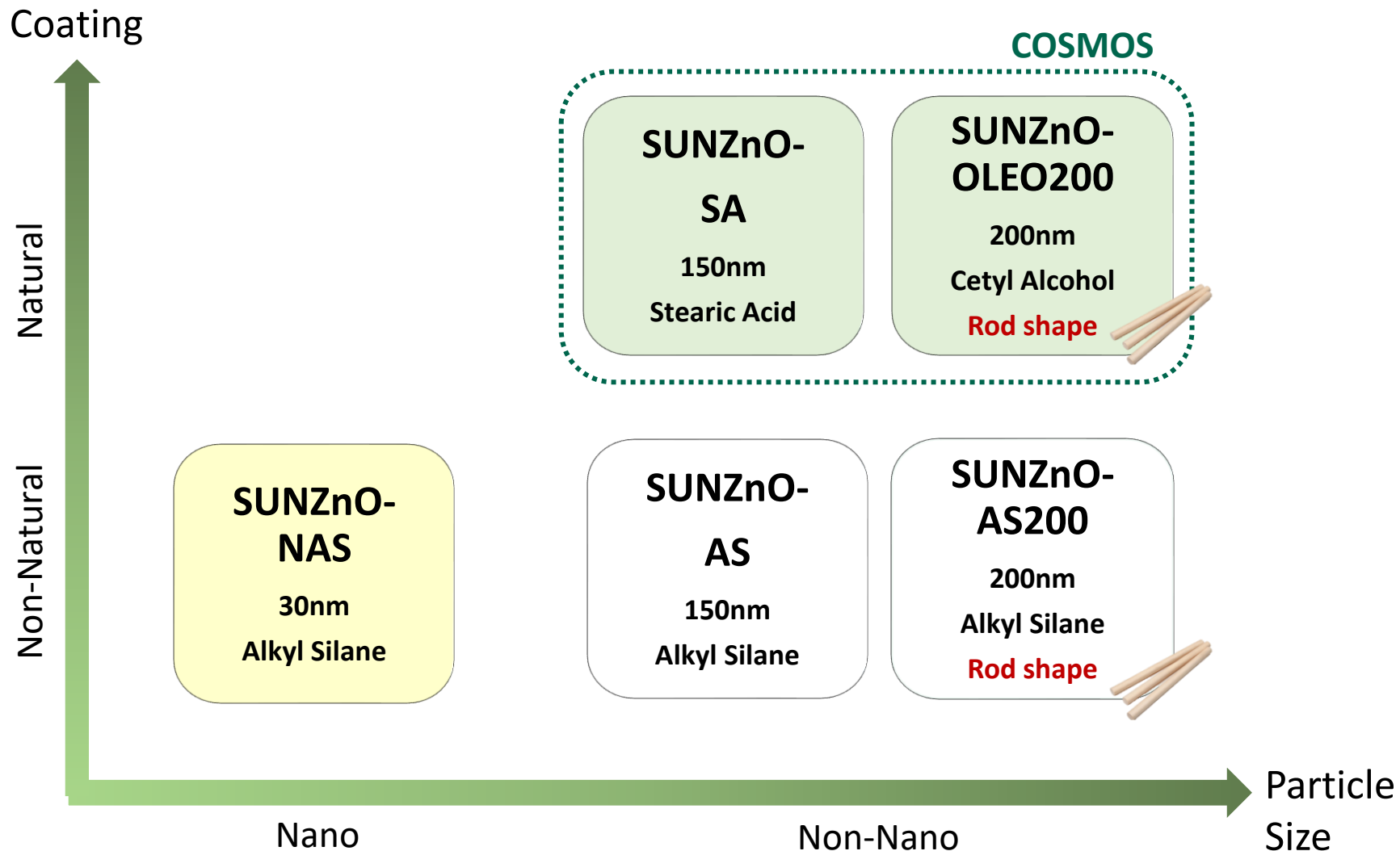
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NDC Package Code	Strength	Dosage Form	Labeler Name	Nonproprietary Name	Substance Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	DEA	Listing Record Certified Through:
71028-1101-1	1 kg/kg	POWDER	SUNJIN BEAUTY SCIENCE 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
71028-1108-1	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 (71028-1108-1)	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	0.5 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	0.5 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	0.35 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

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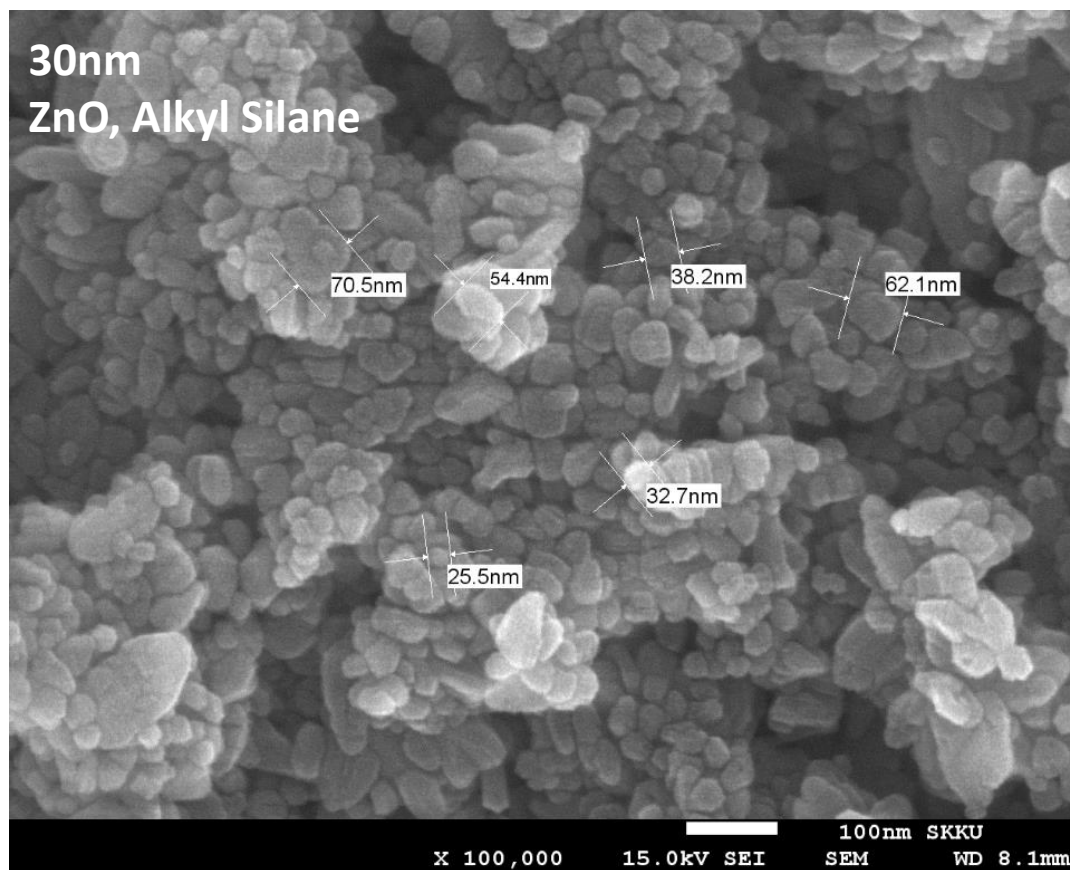
Zinc Oxide Overview



Zinc Oxide Overview

	SUNZnO-NAS	SUNZnO-AS	SUNZnO-200AS	SUNZNO-OLEO200	SUNZNO-SA
ZnO Purity %	97%	97%	97%	96%	95%
ZnO Coating	Triethoxycaprylsilane	Triethoxycaprylsilane	Triethoxycaprylsilane	Cetyl Alcohol	Stearic Acid
Particle size	30nm	150nm	200nm	200nm	150nm
Shape (Morphology)	Round	Round	Rod 	Rod 	Round
Transparency by White index	40.66			34.74	51.05
Remarks	SCCS Compliant Nano ZnO	Non-nano	Non-nano	Non-nano COSMOS RSPO	Non-nano COSMOS RSPO

SUNZnO-NAS

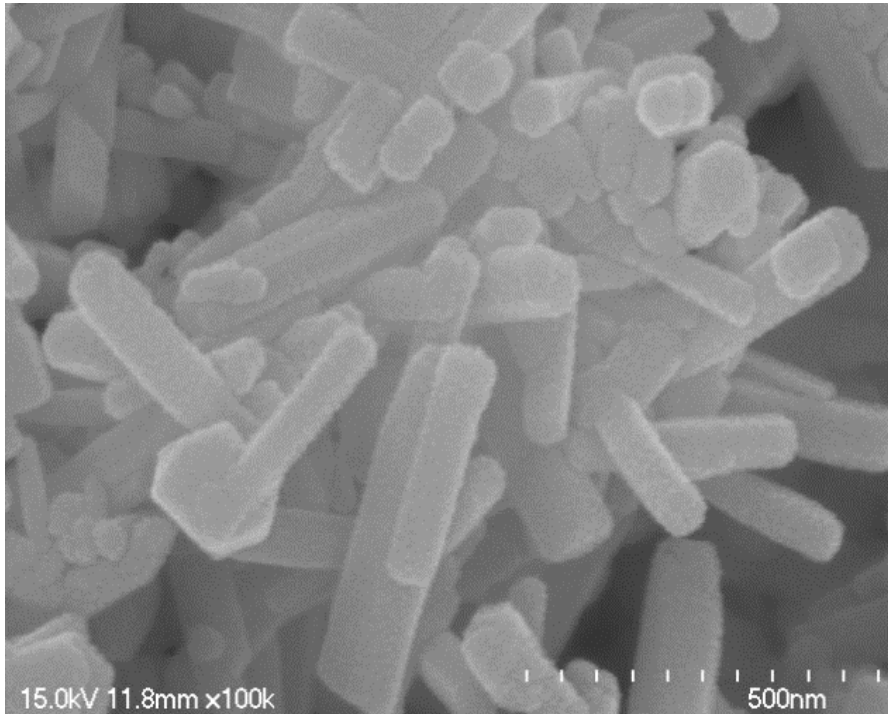


1.8MT/batch



SUNZnO-OLEO200

World-First **Rod Shape** Zinc Oxide with **Cetyl Alcohol** Coating
Non-Nano



Patent # : 1017687720000 / Korean Intellectual Property Office (KIPO)

Why Rod Shape?

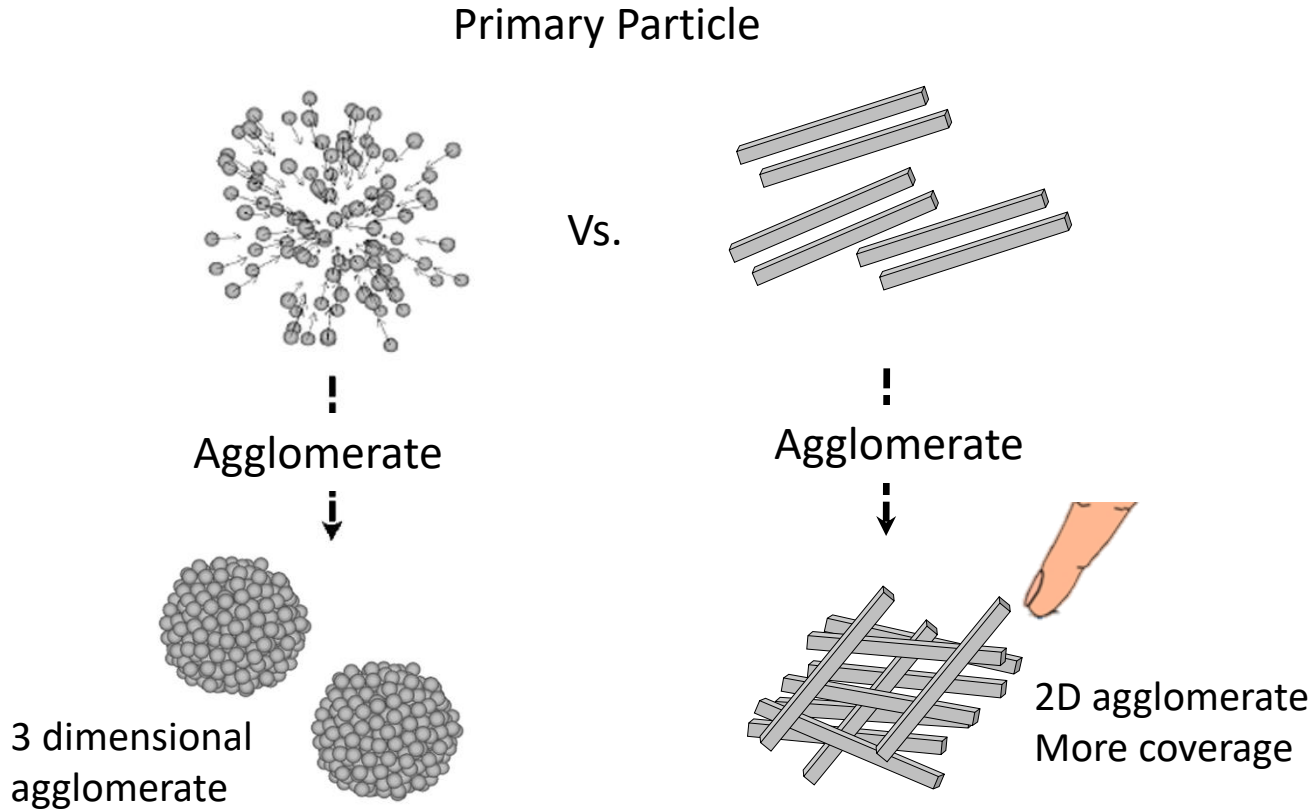
1. Better Transparency
2. Better UV performance
3. More Creamy Feeling
4. Better Spread

Why Cetyl Alcohol Coating?

1. Natural
2. Ether bond formation
more stable than ester
bonding



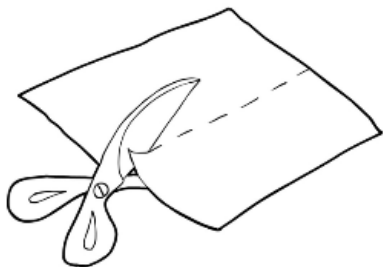
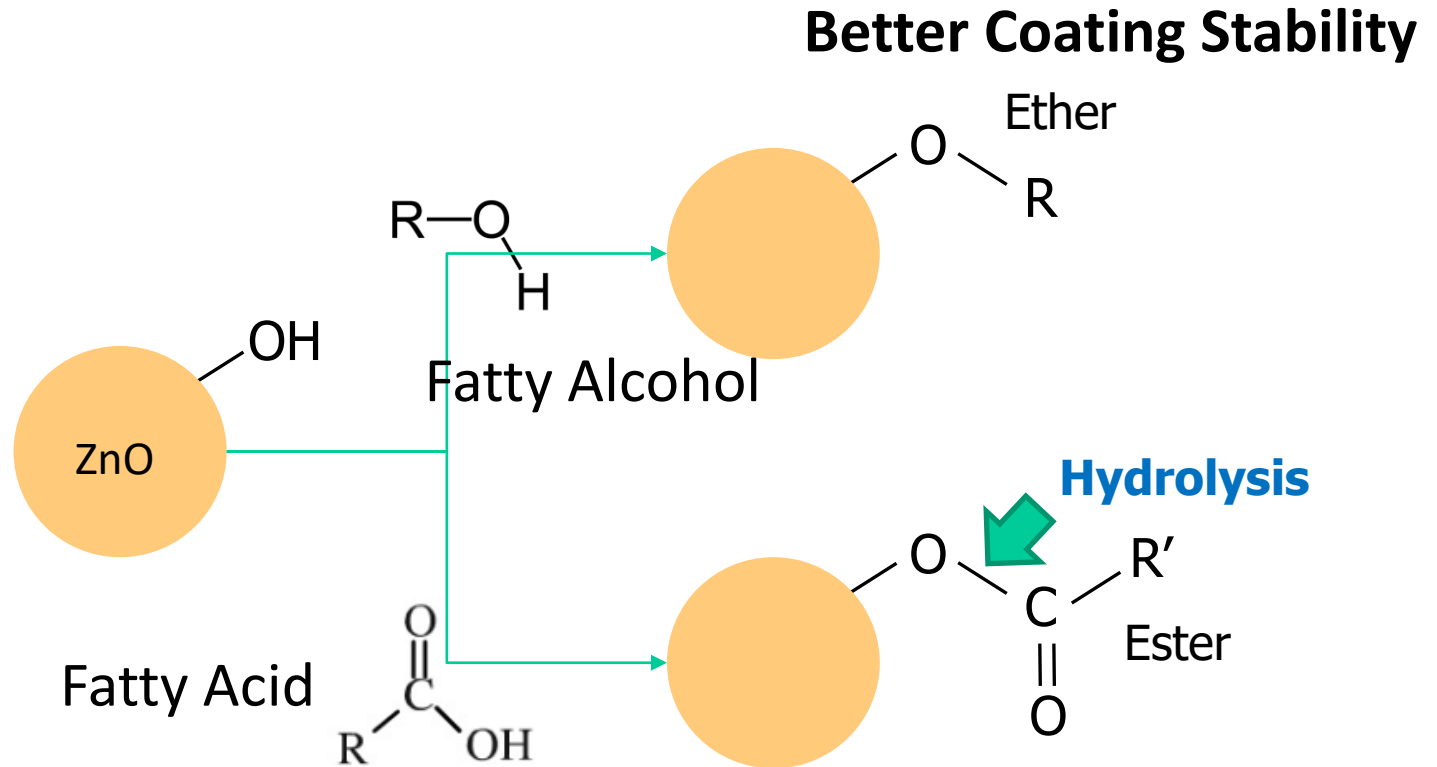
Why Rod Shape?



- Better Transparency
- Better UV performance
- More creamier
- Better spread

Agglomeration by physical interaction of primary particles
Aggregation, new formed particle by primary particles .

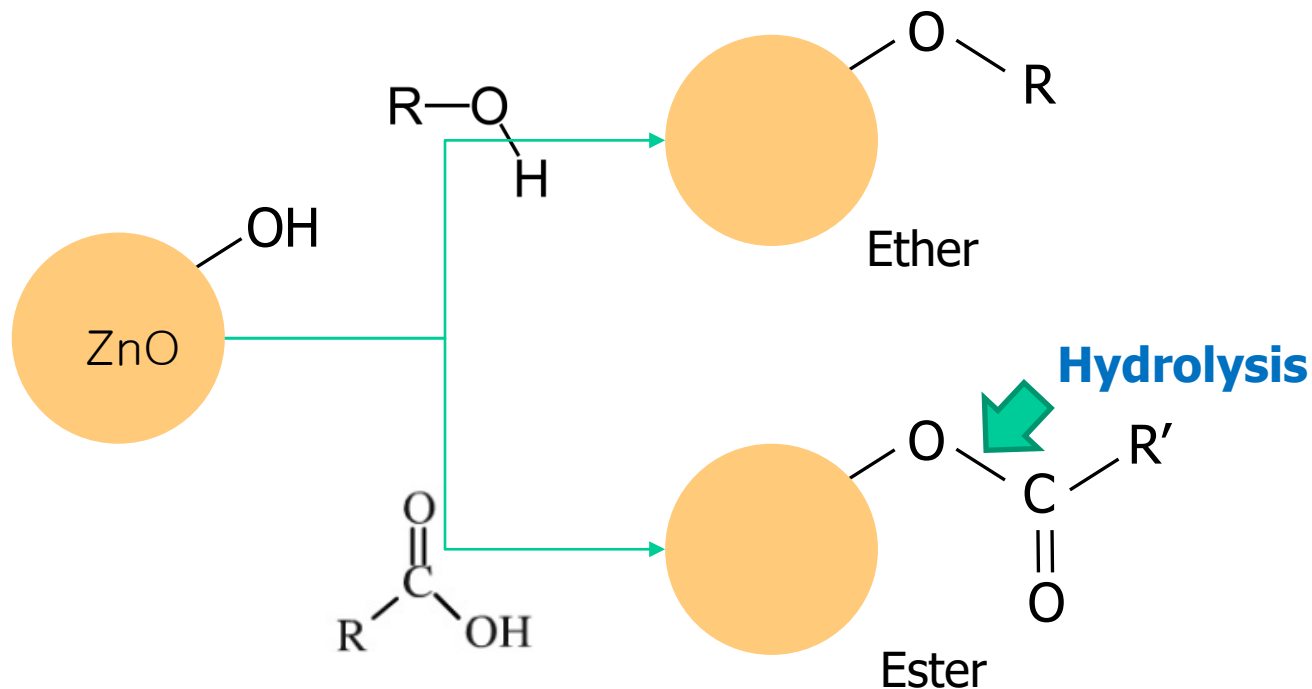
Why Cetyl Alcohol?



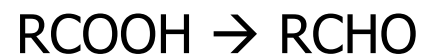
Conventionally the most common natural coating material has been fatty acid but ester functional group is susceptible to hydrolysis

SUJIN is the first company introducing fatty alcohol coating to Inorganic UV filters

No Bad odor

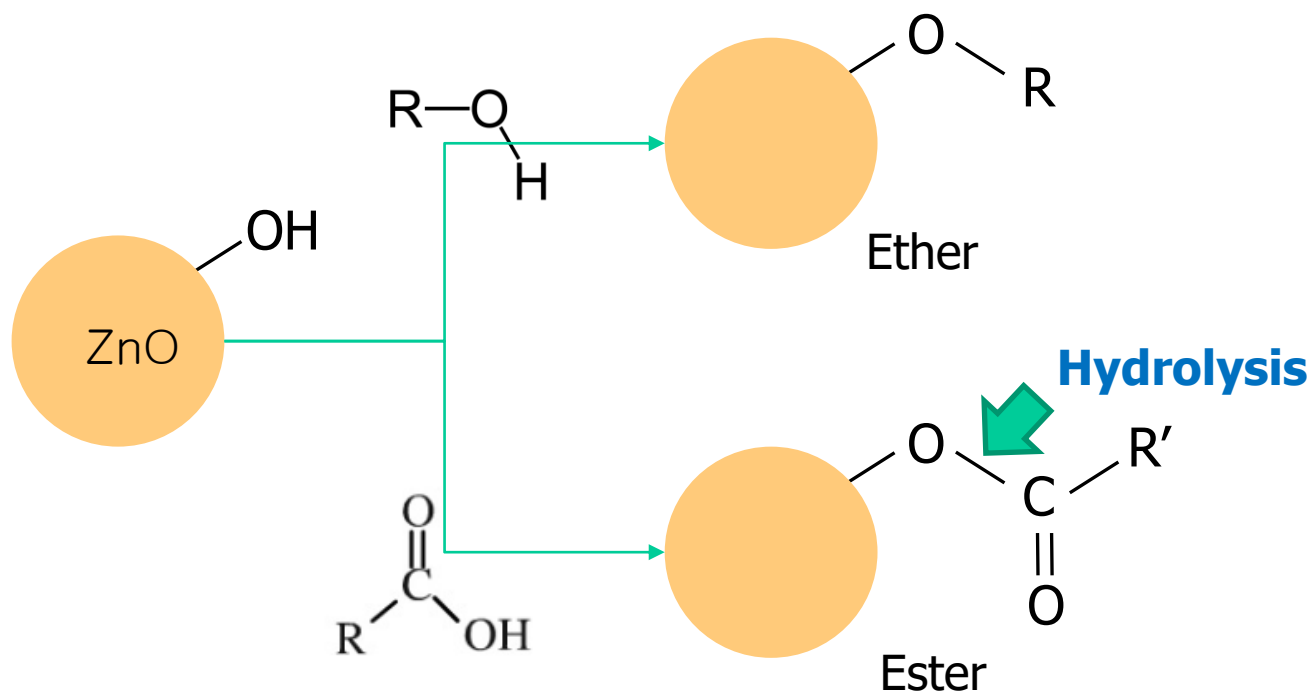


Bad odor



RCOOH usually double bond
inside

No Yellowing

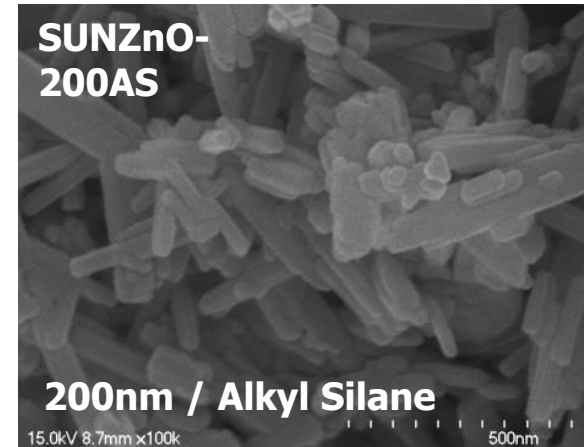
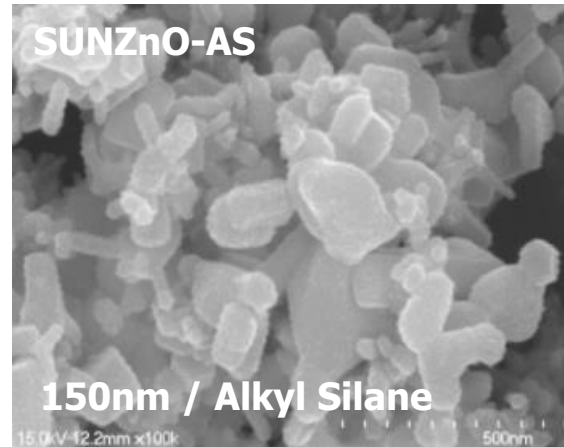
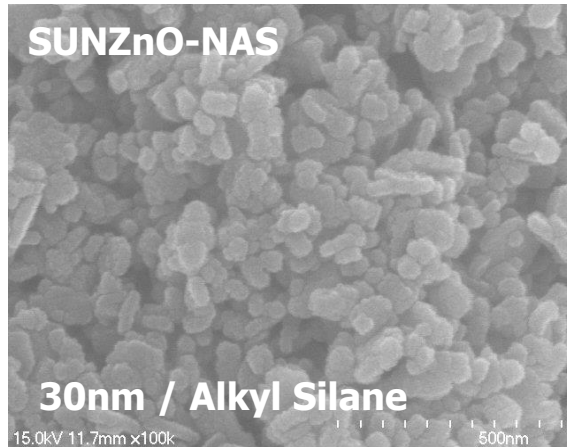


Yellowing by Oxidation

RCOOH usually double bond inside

Zinc Oxide Overview

by SEM



Transparency by White Index

Tested Znic Oxide

#1

Company SUNJIN

Product : SUNZnO-NAS

#2

Company : SUNJIN

Product : SUNZnO-OLEO200

Lot: 19086001

#3

Company : SUNJIN

Product : SUNZnO-OLEO200

Lot: 200262001

#4

Company : "E"

Product : "Z"

#5

Company : "D"

Product : "P"

#6

Company : "B"

Product : "Z"



NIPPON DENSHOKU
COLOR METER ZE 2000

*The Higher White index,
the less transparent*

#1. SUNJIN
ZnO-NAS

38.08

#2. SUNJIN
ZnO-OLEO200

39.23

#3. SUNJIN
ZnO-OLEO200

38.24

#4. Company "E"
Product "Z"

36.36

#5. Company "D"
Product "P"

45.32

#6. Company "B"
Product "Z"

48.43

In vivo result from W/O formula

Test Result	SUNZNO-NAS	SUNZNO-OLEO200 Lot: 19086001	SUNZNO-OLEO200 Lot: 200262001	Company "E" Product "Z"	Company "D" Product "P"	Company "B" Product "Z"
in vivo SPF	30.00	30.00	30.00	30.00	30.00	29.40
Determine						
in vivo PA	9.20	10.57	10.57	9.20	9.20	10.57
Determine						

Panel condition

Name	LYJ
Age	25
Sex	F
Skin type	II

Hydrophobicity Result

Tested Znic Oxide

#1

Company : SUNJIN

Product : SUNZnO-NAS

#2

Company : SUNJIN

Product : SUNZnO-OLEO200

Lot: 19086001

#3

Company : SUNJIN

Product : SUNZnO-OLEO200

Lot: 200262001

#4

Company : "E"

Product : "Z"

#5

Company : "D"

Product : "P"

#6

Company : "B"

Product : "Z"

