

RAW MATERIAL AND PACKAGING MATERIAL EVALUATION FORM

Material Identification

Apply Component Release Sticker and/or Label Here

Item 300536

STEARIC ACID POWDER BULK - KOSHER

Old Part Number 2000001098

PO Number 2021-00-40597

NutraStar Lot 21012890

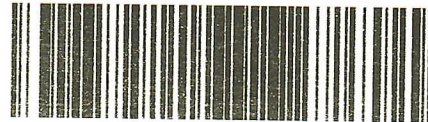
Received 06/08/2021

Vendor Em Sergeant

Vendor Lot PN21309-004556

Expires 02/07/2023

NET WT: 22.680 KG



QUALITY:

SPECIFICATION VERSION: 3

Review test results generated by a QC Technician, External Laboratory or stated on the supplier's CoA with the listed specification. Record the review by using the respective specification form.

REVIEW COMPLETED BY: Christina Lopez DATE: 06/08/21

DISPOSITION:

<input checked="" type="checkbox"/> RELEASED – This lot (batch) is approved for use in production, further processing, or distribution.	Quality Signature/Date: <u>manivelly 06/08/2021</u>
<input type="checkbox"/> RELEASED WITH RESTRICTIONS – This lot (batch) is released for use in production, further processing, or distribution, subject to the following conditions.	Management Signature/Date:
<input type="checkbox"/> REJECTED – This lot (batch) is prohibited from use in production, further processing, or distribution due to the following reasons.	Quality Signature/Date:



RAW MATERIAL SPECIFICATION AND ANALYSIS FORM

MATERIAL DESCRIPTION

SPECIFICATION VERSION: B

Storage Conditions: Ambient

Material Name: Stearic Acid Powder Bulk

Item Number: 300536

Lot Number: 21012890

Primary Vendor: Em Sergeant

Category: Chemical Entity

REQUIRED TESTS AND EXAMINATION

1. APPEARANCE:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Color	VISUAL	White to faintly yellow	White
Texture	MACROSCOPIC	Fine Powder	Conforms

2. IDENTIFICATION:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Identity	M0034	Conforms	94%

3. STRENGTH (POTENCY):

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Assay	COA	N/A	N/A

4. PHYSICAL CHARECTERISTIC:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Bulk Density	COA	>0.4 g/mL	samples
Particle Size	COA	N/A	N/A

5. COMPOSITION (EXCIPIENT/CARRIER):

SPECIFICATION	Verified
N/A	N/A



RAW MATERIAL SPECIFICATION AND ANALYSIS FORM

6. CONTAMINANTS:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Microbiology	COA	TAMC <1,000 cfu/g TYMC <100 cfu/g E. Coli Absent/10g Salmonella Absent/10g	Complies
Heavy Metals	COA	Arsenic < 15µg/g Cadmium < 5µg/g Lead < 5µg/g Mercury < 2µg/g	Complies

7. QC NOTES:

Bulk Density	N/A
Particle Size	N/A
Strength	N/A
Micro	N/A
Metals	N/A

8. REVISION HISTORY:

Version	Effective Date	Reason for Change
A	06/05/2018	New Document
B	01/05/2021	Updated Template

9. DOCUMENT FORM HISTORY (See form history in SOP 03.011-F03.004)

Prepared by:	Original Signatures on File
Approved by:	Original Signatures on File



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CERTIFICATE OF ANALYSIS

PRODUCT **STEARIC ACID 50 NF* POWDER
(TRIPLE PRESSED, VEGETABLE)**
LOT No. PN21309-004556
MFG DATE: FEBRUARY 08, 2021
EXP DATE: FEBRUARY 07, 2023
COUNTRY OF ORIGIN MALAYSIA

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<u>TEST ITEMS</u>	<u>SPECIFICATIONS</u>	<u>RESULTS</u>
Appearance	Fine powder	Complies
Color	White to faintly yellowish	Complies
Identification		
A: Freezing Point	Meets the requirements	Complies
B: Acid Value	194 – 212 mg KOH/g	208.65 mg KOH/g
C: Retention Time	Retention time of major peaks matches the standards	Complies
Color of Solution	Meets NF requirements	Complies
Arsenic (As)	1.0 ppm Max	ND (< 0.05 ppm)
Cadmium (Cd)	2.0 ppm Max	ND (< 0.02 ppm)
Lead (Pb)	0.5 ppm Max	ND (< 0.02 ppm)
Mercury (Hg)	0.1 ppm Max	ND (< 0.02 ppm)
Nickel (Ni)	0.1 ppm Max	ND (< 0.02 ppm)
Heavy Metals	10 ppm Max	< 5 ppm
Acidity	No red color develops	Complies
Mineral Acid (old NF)	Pass NF Test	Pass
Neutral Fat (old NF)	Pass NF Test	Pass
Color, Lovibond 5.25"	0.1R/1.0Y Max	0.1R/0.9Y
Iodine Value	.5 gI ₂ /100g Max	0.30 gI ₂ /100g
Unsaponifiable Matter	0.5 % Max	0.29%
Saponification Value	206 – 211 mg KOH/g	210.3 mg KOH/g
Freezing Point	53.0 – 59.0°C	55.6°C
Titer (Congealing Temp)	54°C – 56.6°C	55.6°C
% Trans @ 440 / 550 nm	92% / 93% Min	95.9% / 97.1%
Residue on Ignition	0.1 % w/w Max	0.03% w/w
Moisture	0.3% Max	0.03%
Residual Solvents	Meet USP<467> Standard	Complies
Through 100 Mesh	99 – 100%	100%
Bulk Density	410 – 485 kg/m ³	430.6 kg/m ³
Elemental Impurities Limits	NMT Daily Dose PDE	Complies



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MICROBIOLOGICAL – Quarterly testing

Total Aerobic Plate Count	20 cfu/g Max	< 10 cfu/g
Total Yeast and Mold Count	10 cfu/g Max	< 10 cfu/g
E. coli	Absent	Absent
Salmonella (25 g)	Absent	Absent
Staphylococcus aureus	Absent	Absent

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FATTY ACID CONTENT

Assay of C14	1.5% Max	0.00%
Assay of C16	52 – 56%	55.11%
Assay of C18	42 – 48%	44.55%
Assay of C16 + C18	NLT 90.0%	99.66%

This product is non-GMO (derived from Palm/Palm kernel oil).

This material is Kosher.

*** Current USP/NF is USP41 / NF 36 (officially on May 01, 2018)**

This is a copy of the original Manufacturer's/Supplier's Certificate of Analysis

Ivaylo Balabanov, Quality Assurance