

RAW MATERIAL, LABEL AND PACKAGING MATERIAL EVALUATION FORM

Item 300570

VITA PRESS POWDER(DI CALCIUM PHOSPHATE UNMILLED)

Old Part Number 2000001158

PO Number 2020-00-32151

NutraStar Lot 20023281

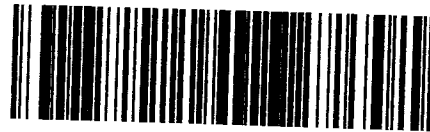
Received 09/21/2020

Vendor CELLMARK

Vendor Lot D2007-3

Expires 05/26/2024

NET WT: 25.000 KG



QUALITY CONTROL:

SPECIFICATION VERSION: B

NET QUANTITY _____

NOTEBOOK REFERENCE: WC

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 checklist below.

ATTRIBUTE	SPECIFIC CONFORMANCE		
APPEARANCE	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
ORGANOLEPTIC	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input checked="" type="checkbox"/> N/A
IDENTITY	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
STRENGTH	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
PURITY	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
COMPOSITION	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
CONTAMINANTS	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A

COMPLETED BY: Delene Camera DATE: 09/22/2020

DISPOSITION:

<input checked="" type="checkbox"/> RELEASED	SIGNATURE / DATE: <u>maria veliz 09/23/2020</u>
<input type="checkbox"/> REJECTED	



RAW MATERIAL SPECIFICATION AND ANALYSIS FORM

MATERIAL DESCRIPTION

SPECIFICATION VERSION: B

SHELF LIFE: 4 years

Material Name: Vita Press Powder

ANS Item Number: 300570

Primary Vendor: Anmar International Ltd

Alternative Suppliers: N/A

Lot Number: 20023281

Cellmark

Category: Chemical Entity

Storage Conditions: Ambient

LABELING REQUIREMENTS:

N/A KOSHER HALAL LIST ALLERGENS: _____

REQUIRED TESTS AND EXAMINATION

1. APPEARANCE:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
COLOR	VISUAL	White	Conforms
TEXTURE	MACROSCOPIC	Powder	Complies
Organoleptic	OLFACTORY	N/A	N/A

2. IDENTIFICATION:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Identity	USP Dibasic Calcium Phosphate Dihydrate Test A	Conforms	Conforms

3. STRENGTH:

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

4. COMPOSITION:

SPECIFICATION	Verified
N/A	N/A



RAW MATERIAL SPECIFICATION AND ANALYSIS FORM

5. CONTAMINANTS:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Microbiology	COA	TAMC <1000 cfu/g TYMC <100 cfu/g E. Coli Absent/10g Salmonella Absent/10g	Confirms
Heavy metals	COA	Arsenic < 15µg/unit Cadmium < 5µg/unit Lead < 5µg/unit Mercury < 2µg/unit	Confirms.

6. JUSTIFICATIONS (*Example)

Appearance	COA
Identity	USP Dibasic Calcium Phosphate Dihydrate Test A
Strength	COA
Composition	COA
Micro	COA
Metals	COA

7. INGREDIENT SPECIFICATION REVISION HISTORY

Version	Effective Date	Reason for Change
A	06-21-18	New Document
B	08-06-18	Updated Description

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

Prepared by:	Original Signatures on file
Approved by:	Original Signatures on file

Equipment:

Name	ID	Notes
Balance	796	✓
Vortex	197	✓
Centrifuge	W/A	
Timer		
Oven		
Other:		
Other:		
AC		09/22/2020

Procedure:

Sample ID	Weight	Diluent	Diluent volume	Notes
Vita press sample	0.1 g	2N HCl	10 ml	✓
W/A				
AC			09/22/2020	

Testing solutions:

Name	Weight/Volume	Diluent	Final Volume	Notes
2N HCl	1.642 ml	10 ml	water	(1st 2.5 ml water then HCl)
W/A				
AC			09/22/2020	

Data Collection:

2.5ml Ammonia TS is added to sample solution - 5ml
of Ammonium oxalate TS is added - white ppt becomes.

AC 09/22/2020

Conclusion:

- Conforms
- Non-conforms
- Further Testing

Notes:

Passes Id test.

AC 09/22/2020

Quality Review:

maria vitez 09/23/2020

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CERTIFICATE OF ANALYSIS

PRODUCT:	VitaPress® Dicalcium phosphate Dihydrate, Unmilled		
GRADE :	Pharmaceutical Grade		
TESTING BASIS :	USP42	LOT NUMBER:	D2007-3
PRODUCTION DATE:	2020/05/26	EXPIRY DATE :	4years
QUANTITY:	20MT	CUSTOMER:	CellMark USA LLC
ITEM CODE:	074		

<u>PROPERTY</u>	<u>TEST METHODS</u>	<u>SPECIFICATIONS</u>	<u>TEST RESULTS</u>
Appearance	Visual	White, free flowing granule powder, no visible impurities	OK
Odor	Visual	Odorless	Pass test
Physical Test			
Sieve Analysis Through 20 mesh %	PDT-0203	100	100
Through 100 mesh %	PDT-0203	Report only	14.75
Through 325 mesh %	PDT-0203	Typically <1	0.80
Chemical Test			
Identification A	USP	Pass test	Pass test
Identification B	USP	Pass test	Pass test
Assay (CaHPO ₄ ·2H ₂ O) %	USP	98.0- 103.0	99.75
Assay (Ca)(without ignition) %	USP	23.2-23.3 target value	23.2
Assay (CaO) %	USP	32.45-32.55 target value	32.50
Assay (P) %	GB24568	17.7min	18.12
Loss on Ignition %	USP<733>	24.5 – 26.5	26.12
Loss on Drying %	GB24568	0.6 max	0.14
PH (20% slurry)	GB24568	7.0-7.8	7.58
Impurities			
Carbonate	USP	Pass test	Pass test
Chlorides(as Cl) %	USP<221>	0.25 max	<0.02
Sulfate (as SO ₄) %	USP<221>	0.5max	<0.02
Arsenic (As) mg/Kg	USP<211>	3 max.	< 1
Barium	USP	Pass test	Pass test
Limit of Acid-Insoluble Substance %	USP	0.2 max	0.04
Limit of Fluoride mg/Kg	USP	50 max	<20
Heavy Metals (as Pb) mg/Kg	GB24568	10 max	<10
Iron (as Fe) mg/Kg	GB24568	50 max	<50
Lead mg/Kg	ICP-MS	0.5 max.	0.20
Mercury mg/Kg	ICP-MS	0.1 max	ND
Cadmium	ICP-MS	1.0 max	0.09
Microbiology			
TPC cfu/g	GB24568	1000 cfu/g max.	< 10
Yeast and Mold cfu/g	GB24568	100 cfu/g max.	< 10
E. coli cfu/g	GB24568	Negative	Negative
Staph Aureus cfu/g	GB24568	Negative	Negative

Conclusion: PASS TEST

Testers of the Lab: Han Jing

Head of the Lab: Shen Jiangli

Jiangsu Chengxing Phosph-Chemicals Co., Ltd.
618 Meiyuan Road Jiangyin Jiangsu China
T: 86 510 86281316 F: 86 510 86281884



Dicalcium Phosphate Dihydrate

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 12/19/2019

Supersedes: 08/19/2019

Version: 2.0

SECTION 1: Identification

1.1. Identification

Product form : Substance
 Trade name : Dicalcium Phosphate Dihydrate
 Chemical name : Calcium hydrogenphosphate dihydrate
 CAS-No. : 7789-77-7
 Product code : 45070, 45318, 45319, 45063
 Formula : HCaO4P.2H2O
 Other means of identification : EC number: 231-826-1[anhydrous]

1.2. Recommended use and restrictions on use

No additional information available

1.3. Supplier

Supplier

CellMark USA, LLC (Ingredients)
 2 Corporate Drive, 5th Floor
 Shelton, CT 06484 - USA
 T +1 203-336-8330

1.4. Emergency telephone number

Emergency number : 1-800-535-5053 (US, Canada, Puerto Rico) or 1-352-323-3500 (international)

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Not classified

2.2. GHS Label elements, including precautionary statements

GHS US labelling

No labelling applicable

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product Identifier	%	GHS-US classification
Dicalcium Phosphate Dihydrate USA (Main constituent)	(CAS-No.) 7789-77-7	98 - 103	Not classified

Full text of hazard classes and H-statements : see section 16

3.2. Mixtures

Not applicable

SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.
 First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention if you feel unwell.
 First-aid measures after skin contact : Wash skin with plenty of water. If skin irritation occurs: Get medical advice/attention.
 First-aid measures after eye contact : Rinse cautiously with water for several minutes. If eye irritation persists: Get medical advice/attention.
 First-aid measures after ingestion : Do not give an unconscious person anything to drink. Rinse mouth out with water. Call a POISON CENTER/doctor if you feel unwell.

Dicalcium Phosphate Dihydrate

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4.2. Most important symptoms and effects (acute and delayed)

No additional information available

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. The product is not flammable.

5.2. Specific hazards arising from the chemical

Fire hazard : Toxic fumes may be released. Not flammable.

5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions : Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate unnecessary personnel. Use personal protective equipment (PPE). Prevent product from entering drains. Avoid dust formation.

6.1.1. For non-emergency personnel

Emergency procedures : Only qualified personnel equipped with suitable protective equipment may intervene. Evacuate unnecessary personnel. Avoid contact with skin and eyes. Avoid dust formation.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Pick-up and arrange disposal without creating dust. Sweep up or vacuum up the product. Keep in suitable, closed containers for disposal.

Methods for cleaning up : Mechanically recover the product.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Avoid formation of dust. Avoid breathing dust, mist or spray.

Precautions for safe handling : Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Ensure good ventilation of the work station. Avoid the build-up of electrostatic charge.

Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Store in dry, cool, well-ventilated area. Keep away from sources of ignition.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Dicalcium Phosphate Dihydrate (7789-77-7)

No additional information available

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8.2. Appropriate engineering controls

- Appropriate engineering controls : Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Use personal protective equipment (PPE).
- Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Hand protection:

Protective gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Physical state : Solid
- Appearance : Granular powder.
- Colour : white
- Odour : odourless
- Odour threshold : No data available
- pH : 6.8 - 8.1
- Melting point : No data available
- Freezing point : Not applicable
- Boiling point : No data available
- Flash point : No data available
- Relative evaporation rate (butylacetate=1) : No data available
- Flammability (solid, gas) : Non flammable.
- Vapour pressure : No data available
- Relative vapour density at 20 °C : No data available
- Relative density : 2.306 Not applicable
- Molecular mass : 172.09 g/mol
- Solubility : Water: 0.02 g/l at 25 °C
- Log Pow : No data available
- Auto-ignition temperature : Not applicable
- Decomposition temperature : No data available
- Viscosity, kinematic : No data available
- Viscosity, dynamic : No data available
- Explosive limits : Not applicable
- Explosive properties : No data available
- Oxidising properties : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

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10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

Strong acids.

10.6. Hazardous decomposition products

Phosphorus oxides. calcium oxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified (No data available)
Acute toxicity (dermal)	: Not classified (No data available)
Acute toxicity (inhalation)	: Not classified (No data available)
Skin corrosion/irritation	: Not classified (No data available) pH: 6.8 - 8.1
Serious eye damage/irritation	: Not classified (No data available) pH: 6.8 - 8.1
Respiratory or skin sensitisation	: Not classified (No data available)
Germ cell mutagenicity	: Not classified (No data available)
Carcinogenicity	: Not classified (No data available)
Reproductive toxicity	: Not classified (No data available)
STOT-single exposure	: Not classified (No data available)
STOT-repeated exposure	: Not classified (No data available)
Aspiration hazard	: Not classified (No data available)
Viscosity, kinematic	: No data available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No data available on ecotoxicity.

12.2. Persistence and degradability

Dicalcium Phosphate Dihydrate (7789-77-7)

Persistence and degradability	No data available.
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12.3. Bioaccumulative potential

Dicalcium Phosphate Dihydrate (7789-77-7)

Bioaccumulative potential	No bioaccumulation data available.
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12.4. Mobility in soil

Dicalcium Phosphate Dihydrate (7789-77-7)

Ecology - soil	No data available.
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12.5. Other adverse effects

Other information : No data available.

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container in accordance with licensed collector's sorting instructions.

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Product/Packaging disposal recommendations : Offer surplus and non-recyclable solutions to a licensed disposal company.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

Department of Transportation (DOT)
In accordance with DOT

Not regulated

Transportation of Dangerous Goods

Transport by sea

Not regulated

Air transport

Not regulated

SECTION 15: Regulatory information

15.1. US Federal regulations

Dicalcium Phosphate Dihydrate (7789-77-7)

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

Dicalcium Phosphate Dihydrate (7789-77-7)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

National regulations

No additional information available

15.3. US State regulations

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Data sources : SDS of suppliers.

SDS US (GHS HazCom 2012)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.