



TECHNICAL DATA PACKAGE

CALCIUM D-PANTOTHENATE

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SUANFARMA

PRODUCT SPECIFICATION SHEET

REVISION 1.2020

IDENTIFICATION

NAME	CALCIUM D-PANTOTHENATE
SYNONYMS	Dexpanthenol, Pantothenic Acid, Calcium Pantothenate, Vitamin B5
FORMULA	C ₉ H ₁₇ NO ₅
PRODUCT CODE	CALDP
SHELF LIFE	36 Months
MOLECULAR WEIGHT	219.23
CAS NUMBER	137-08-6
SOLVENT USED	Methanol
COUNTRY OF ORIGIN	China

PHYSICAL & CHEMICAL ANALYSIS

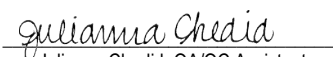
PARAMETER	SPECIFICATION	METHODS
1. APPEARANCE COLOR	Powder White	USP 42 USP 42
2. IDENTIFICATION	Positive to IR reference standard	USP 42
3. IDENTIFICATION OF CALCIUM	Meets all requirements	Meets all requirements
4. SPECIFIC ROTATION (DRIED BASIS)	+25.0° ~ +27.5°	USP 42
5. ALKALINITY	No pink color is produced within 5 seconds	USP 42
6. LOSS ON DRYING	NMT 5.0%	USP 42 (105° for 3 Hours)
7. RESIDUAL SOLVENTS (Methanol)	NMT 0.3%	USP 42
8. HEAVY METAL LEAD ARSENIC CADMIUM MERCURY	NMT 0.5 ppm NMT 1.0 ppm NMT 0.5 ppm NMT 0.1 ppm	AA or ICP-MS AA or ICP-MS AA or ICP-MS AA or ICP-MS
9. ASSAY (On Dried Basis) CALCIUM CONTENT	98% ~ 102% 8.2% ~ 8.6%	USP 42 USP 42

MICROBIOLOGY CONTROL

TOTAL PLATE COUNT	NMT 1,000 cfu/g	USP 42
YEAST & MOLD	NMT 100 cfu/g	USP 42
COLIFORM	NMT 100 cfu/g	USP 42
E. COLI	Negative	USP 42
SALMONELLA	Negative	USP 42
STAPHYLOCOCCUS	Negative	USP 42

STORAGE CONDITIONS: PRESERVE IN TIGHTLY-SEALED CONTAINERS UNDER COOL, DRY CONDITIONS. AVOID EXCESSIVE EXPOSURE TO SUNLIGHT.

MANUFACTURING SITE: THIS MATERIAL HAS BEEN CUSTOM MADE AND PROCESSED AT NO. 9 SHANGGUAFAN, JINNAN DISTRICT LIN'AN, ZHEJIANG. CHINA 311300 TO MEET SUAN FARMA, INC. SPECIFICATIONS.


Julianna Chedid, QA/QC Assistant
DATE PRINTED: May 1, 2020



ALLERGEN STATEMENT

We, Suan Farma, Inc., hereby declare that **Calcium D-Pantothenate** (product code: **CALDP**) is free of the following allergens, nor are these allergens present in the manufacturing facility:

- Milk and milk products (E.g. casein, lactose, whey)
- Egg and egg products
- Fish (e.g. bass, flounder, cod)
- Crustacean shellfish (e.g. crab, lobster, shrimp, crayfish)
- Tree nuts (e.g. almond, pecan, walnut, coconut, hazelnut, cashew, brazil, pistachio, macadamia)
- Wheat and wheat products (e.g. bran, germ, gluten, flour, starch)
- Gluten (from oats, barley, rye, triticale)
- Peanuts and peanut products (except highly refined oil)
- Soybeans and soybean products (except highly refined oil)
- Sulfites and sulfur dioxide (more than 10mg/kg or 10mg/L expressed as SO₂)
- Celery, mustard (e.g. leaves, flowers, seeds, oil)
- Seeds and seed products (e.g. pine nut, sesame, sunflower, poppy, cottonseed) (except refined oil)
- FD&C yellow#5 (tartrazine)
- Monosodium glutamate

Regards,

Julianna Chedid

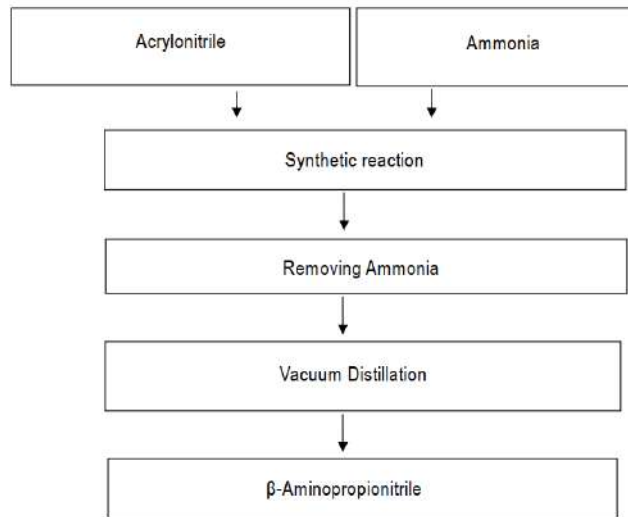
Julianna Chedid
QA/QC Assistant
November 2019

MANUFACTURING PROCESS FLOW CHART

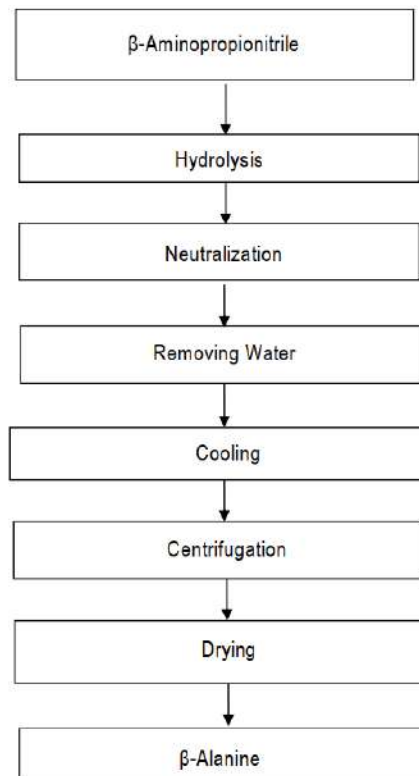
Product Name: Calcium D-Pantothenate

Product Code: CALDP

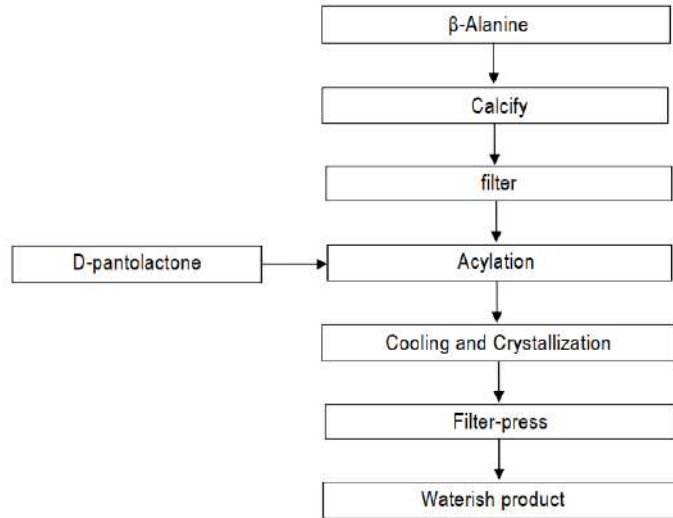
Step 1: Preparation of Beta-Aminopropionitrile



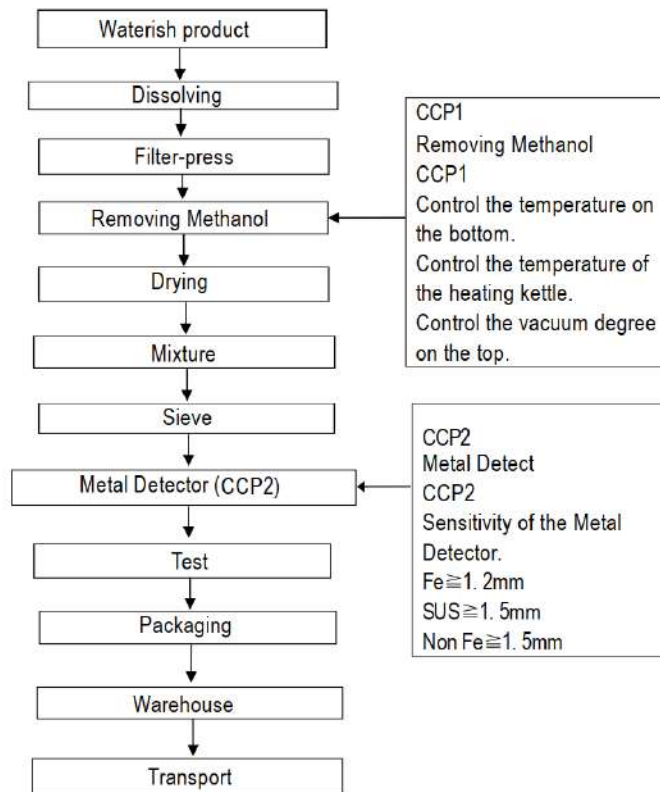
Step 2: Hydrolysis of Beta-Aminopropionitrile to Beta-Alanine



Step 3: Synthesis of Calcium D-Pantothenate



Step 4: Finished product





SAFETY DATA SHEET

REVISION 01.2019

SECTION 1: PRODUCT & COMPANY IDENTIFICATION

Product identifier:

Substance name: CALCIUM D-PANTOTHENATE

Relevant identified uses of the substance or mixture and uses advised against:

Recommended: Widely used in medicine, food, feed, cosmetics and liquid formulations

Uses advised against: None

Supplier Name:

Suan Farma, Inc.
17-09 Zink Place, Unit 7 Fair Lawn, NJ 07410
Phone: 201-343-1188
FAX: 201-343-1102
E-mail: adminus@suanfarma.com

Emergency Phone Number: CHEMTREC (24-hr Access) 800-424-9300;
International CHEMTREC, call: 703-527-3887

SECTION 2: HAZARD(S) IDENTIFICATION

Classification of the substance or mixture:

Classification according to Regulation (EC) No. 1272/2008 [CLP]: Not classified

Label elements:

Symbols/Pictograms: None
Signal word: None
Hazard Statements: Not applicable
Precautionary Statements: Not applicable

Other hazards: No information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Substances:

Chemical Name	EC Number	CAS Number	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Calcium D-Pantothenate	205-278-9	137-08-6	98.0~102.0	Not classified
β -alanine	203-536-5	107-95-9	≤ 1	Not classified
methanol	212-378-6	67-56-1	≤ 0.3	Not classified

SECTION 4: FIRST AID MEASURES

Description of first aid measures

General advice: If symptoms persist, call a physician.

Inhalation: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention if you feel unwell.

Skin Contact: Wash off immediately with soap and plenty of water while removing all contaminated

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clothes and shoes. Wash contaminated clothing before reuse. If skin irritation persists, call a physician.

Eye contact: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Ingestion: Rinse mouth Get medical attention Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed:

No information available

Indication of any immediate medical attention and special treatment needed:

Treat symptomatically

SECTION 5: FIRE FIGHTING MEASURES

Extinguishing media

Suitable extinguishing media: Water spray (fog). Extinguishing powder. Alcohol resistant foam. Dry chemical.

Unsuitable extinguishing media: No information available

Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating and toxic gases and vapors.

Advice for firefighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

Evacuate personnel to safe areas.
Ensure adequate ventilation, especially in confined areas.
Remove all sources of ignition.
Avoid contact with skin, eyes and inhalation of vapors.
Use personal protection recommended in Section 8.

Environmental precautions:

Local authorities should be advised if significant spillages cannot be contained.
Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up:

Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see Section 13).

Reference to other sections:

See Section 7 for more information.
See section 8 for more information.
See section 13 for more information.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:

Handle in accordance with good industrial hygiene and safety practice.
Ensure adequate ventilation, especially in confined areas.
Avoid contact with skin, eyes or clothing.
Wash contaminated clothing before reuse.

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Take precautionary measures against static discharges.
Do not breathe dust/fume/gas/mist/vapors/spray.
Do not eat, drink or smoke when using this product.
Wash thoroughly after handling.
Use personal protection recommended in Section 8.

Conditions for safe storage, including any incompatibilities:

Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep away from heat.
Keep at a temperature not exceeding 25 °C.
Store in accordance with local regulations.

Specific end use(s):

Apart from the uses mentioned in Section 1 no other specific uses are stipulated.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters:

No data available

Derived No Effect Level (DNEL):

No hazard identified

Predicted No Effect Concentration (PNEC):

No hazard identified

Exposure controls:

Engineering Controls:

Use with local exhaust ventilation. Ensure adequate ventilation, especially in confined areas.

Personal protective equipment:

Eye/face protection:

Wear safety glasses with side shields (or goggles).

Hand Protection:

Wear protective nitrile rubber gloves. Ensure that the breakthrough time of the glove material is not exceeded. Refer to glove supplier for information on breakthrough time for specific gloves.

Skin and body protection:

Suitable protective clothing.

Respiratory protection:

No special technical protective measures are necessary.

Environmental exposure controls:

Do not allow into any sewer, on the ground or into any body of water.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Powder
Color	White or almost white
Odor	Odorless
Odor Threshold	Not determined
pH	6.8-8.0
Melting point/freezing point	196°C
Specific optical rotation	+25.5° ~ +27.5°
Boiling point/boiling range	No data
Flash point	No data
Evaporation rate	Not determined
Flammability (solid, gas)	Not determined
Flammability Limit in Air	Not determined
Vapor Pressure	No data



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Vapor density	Not determined
Density	About 0.3g/mL (25/4°C)
Relative density	Not determined
Specific gravity	Not determined
Water solubility	Freely soluble in water
Partition coefficient (LogPow)	Not determined
Autoignition temperature	Not determined
Decomposition temperature	Not determined
Kinematic viscosity	Not determined
Dynamic viscosity	Not determined
Explosive properties	Not an explosive
Oxidizing properties	Not determined

SECTION 10: STABILITY AND REACTIVITY

Reactivity:

No information available.

Chemical stability:

Stable under normal conditions.

Possibility of hazardous reactions:

None under normal processing.

Conditions to avoid:

Heat, flames and sparks.

Incompatible materials:

Strong oxidizing agents. Strong acids. Strong bases.

Hazardous decomposition products:

None under normal use conditions.

SECTION 11: TOXICOLOGY INFORMATION

Information on toxicological effects:

Acute toxicity:	No information available.
Skin corrosion/irritation:	Non-irritating to the skin.
Serious eye damage/eye irritation:	No eye irritation.
Sensitization:	No sensitization responses were observed.
Germ cell mutagenicity:	No information available.
Carcinogenicity:	Not classified
Reproductive toxicity:	No information available.
STOT - single exposure:	No information available.
STOT - repeated exposure:	No information available.
Aspiration hazard:	No information available.

SECTION 12: ECOLOGICAL INFORMATION

Toxicity:

No information available.

Persistence and degradability:

No information available.

Bioaccumulative potential:

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No information available.

Mobility in soil:

No information available

Results of PBT and vPvB assessment:

The substance is not PBT / vPvB

Other adverse effects:

No information available.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods:

Waste from residues/unused products:

Disposal should be in accordance with applicable regional, national and local laws and regulations

Contaminated packaging:

Disposal should be in accordance with applicable regional, national and local laws and regulations.

SECTION 14: TRANSPORT INFORMATION

UN Number	Not regulated
Proper shipping name	Not regulated
Hazard Class	Not regulated
Packing Group	Not regulated
Environmental hazards	Not applicable
Special precautions	No information available
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable

SECTION 15: REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

European Union:

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Take note of Directive 94/33/EC on the protection of young people at work.

Take note of Directive 92/85/EC on the protection of pregnant and breastfeeding women at work.

International Inventories

Component	TSCA	DSL/NDSL	EINECS/ELI NCS	ENCS	IECSC	KECL	PICCS	AICS
Calcium D-Pantothenate 137-08-6	X	X	X	X	X	X	X	X
β-alanine 107-95-9	X	X	X	-	X	X	X	X
Methanol 67-56-1	X	X	X	X	X	X	X	X

"-" Not Listed

"X" Listed

Chemical safety assessment: No information available



SAFETY DATA SHEET

SECTION 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

- TWA - TWA (time-weighted average)
- STEL - STEL (Short Term Exposure Limit)
- Ceiling - Maximum limit value
- TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
- DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
- EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
- ENCS - Japan Existing and New Chemical Substances
- IECSC - China Inventory of Existing Chemical Substances
- KECL - Korean Existing and Evaluated Chemical Substances
- PICCS - Philippines Inventory of Chemicals and Chemical Substances
- AICS - Australian Inventory of Chemical Substances

Full text of H-Statements referred to under section 3

Not classified

Further information

This information is based upon the present state of our knowledge. This SDS had been compiled and is solely intended for this product.

Notice to reader

Employers should use this information only as a supplement to other information gathered by them and should make independent judgement of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty and any use of the product not in conformance with this Safety Data Sheet or in combination with any other product or process is the responsibility of the user.

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information and we assume no liability resulting from its use, users should make their own investigations to determine the suitability of the information for their purposes. In no way shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.



ADDITIONAL INFORMATION

We, Suan Farma, Inc., hereby declare that **Calcium D-Pantothenate** (product code: **CALDP**) is manufactured in accordance with the following guidelines:

- The above material has not been genetically modified or exposed to genetically modified organisms during the production process and is therefore GMO free.
- No animal derived products have been used in the manufacture of the above material, making it free from components which can cause Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE).
- The above material is composed of 100% Calcium D-Pantothenate. It is free of any carriers, binders, excipients, or preservatives.
- The above material has not been irradiated per 7 CFR 205.105(f) requirements with the understanding that "irradiation" shall be defined as outlined in 21 CFR 179.26.
- The above material has not been treated with Ethylene Oxide (ETO) or any other form of chemical sterilization.
- Calcium D-Pantothenate is of synthetic origin. It is suitable for both vegetarian and vegan consumption.

Typical nutritional data for the above material is as follows:

Nutrient (per 100 grams)	Amount	Source	Nutrient (per 100 grams)	Amount	Source
Calories	0		Vitamin D (IU)	0	
Total fat (g)	0		Vitamin E (IU)	0	
Saturated fat (g)	0		Vitamin K (mcg)	0	
Polyunsaturated fat(g)	0		Thiamin (mg)	0	
Monounsaturated fat (g)	0		Riboflavin (mg)	0	
Trans-fatty acids (g)	0		Niacin (mg)	0	
Cholesterol (mg)	0		Vitamin B6 (mg)	0	
Sodium (mg)	0		Folic Acid (mcg)	0	
Potassium (mg)	0		Vitamin B12 (mcg)	0	
Total carbohydrate(g)	0		Biotin (mcg)	0	
Dietary fiber (g)	0		Pantothenic Acid (g)	90.16 ~ 92.92	
Soluble fiber (g)	0		Phosphorus (mg)	0	
Insoluble fiber (g)	0		Iodine (mcg)	0	
Sugars (g)	0		Magnesium (mg)	0	
Moisture (g)	≤ 5.0		Zinc (mg)	0	
Ash (g)	0		Selenium (mcg)	0	
Protein (g)	0		Copper (mg)	0	
Vitamin A (IU)	0		Manganese (mg)	0	
Vitamin C (mg)	0		Chromium (mcg)	0	
Calcium (g)	8.2 ~ 8.6		Molybdenum (mcg)	0	
Iron (mg)	0		Chloride (g)	≤ 0.02	Synthetic

Regards,

Julianna Chedid

Julianna Chedid
 QA/QC Assistant
 Suan Farma, Inc.
 May 2020