

#### **PRODUCT TECHNICAL DOSSIER**

#### **CALCIUM GLUCONATE**

Product Code: P0307

Raw Material Full Name: Calcium Gluconate

Raw Material Full Botanical/Chemical/Latin/Trade Name/Synonyms: Calcium Gluconate

This material is Food Grade: Yes

Vegan / Vegetarian Status:

Limit/Range/Specification: 98.5%-102.0%

**CAS Number:** 299-28-5

EC/EINECS Number: 206-075-8

Molecular Formula for the raw material:  $C_{12}H_{22}CaO_{14}$   $H_2O$ 

Average Molecular weight: 448.39

Solubility in Alcohol: Insoluble in alcohol

**pH:** 6.4-8.3

Loss on Drying: Max 2.0%

Product Code: P0307

Version: 2

QMS





Page 1 of 12

success starts with the finest ingredients...

Registered Office: 203 Lancaster Way Business Park, Ely, Cambridgeshire, CB6 3NX, UK Registered in England No: 3590758 VAT No: GB 711 6598 32

ISO 22000



### **Reducing Substances:**

Max 1.0%

Chloride: Max 0.07%

Sulphate: Max 0.05%

Country of Origin: China

**Country of Origin of the Manufacture:** China

Base Source/Start Material: Gluconic Acid Fermented from Dextrose (Corn) & Calcium Carbonate 100%

Material is: 100%

Shelf Life from Date of Manufacture: Min 2 Years

Storage Conditions: Store in a cool and dry location

Appearance (Fine/Crystals/Crystalline/Hygroscopic): Crystalline/Granular Powder

**Colour:** White to off white

Flavour/Taste: Characteristic

Odour: Characteristic

Product Code: P0307

Version: 2

QMS





Page 2 of 12

success starts with the finest ingredients...

ISO 22000



#### **Microbiological Test**

**Total Viable Count:** Max 1,000cfu/g

Yeast & Moulds: Max 200cfu/g

E.Coli: Absent

Salmonella: Absent

**Heavy Metals** 

Lead (Pb): Max 3ppm

Cadmium (Cd): Max 1ppm

Mercury (Hg): Max 0.1ppm

Arsenic (As): Max 2ppm

Pharmacopeia Standard Used: USP

There are no nuts in this recipe; however we cannot guarantee that the raw materials entering the site are nut free.

Please note that surveillance testing may mean that not all the parameters stated on this specification are tested for every batch.

Product Code: P0307



QMS





Page 3 of 12

success starts with the finest ingredients...

Registered Office: 203 Lancaster Way Business Park, Ely, Cambridgeshire, CB6 3NX, UK Registered in England No: 3590758 VAT No: GB 711 6598 32

ISO 22000

Version: 2



ALLERGENS	Product Contains YES/NO	Listed Item on Site at Manufacturer YES/NO	If YES, Please Comment
Peanuts and Peanut Derivatives (There are no nuts in this recipe, however CCL cannot guarantee that the raw materials entering the site are nut free.)	NO	NO	
Other Nut and Nut Derivatives Almond (Amygdalus communis L.), Hazelnut (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Carya illinoiesis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia) (There are no nuts in this recipe, however CCL cannot guarantee that the raw materials entering the site are nut free.)	NO	NO	
Sesame Seeds and Sesame Seed Derivatives	NO	NO	
Other Seeds and Seed Derivatives (Poppy Seeds, Cotton Seeds, Sunflower Seeds)	NO	NO	
Milk and Milk Derivatives (including lactose)	NO	NO	
Egg and Egg Derivatives	NO	NO	
Cereals and Derivatives containing OR POTENTIALLY CONTAMINATED WITH Gluten (wheat, wheatgrass, faro, freekeh, spelt, kamut, rye, oats, barley, barley grass)	NO	NO	
Soya and Soya Derivatives	NO	NO	
Lupin and Lupin Derivatives	NO	NO	
Mustard and Mustard Derivatives	NO	NO	
Celery or Celery Derivatives (including Celeriac)	NO	NO	
Fish and Fish Derivatives	NO	NO	
Molluscs and their Derivatives	NO	NO	
Crustaceans and their Derivatives	NO	NO	
Sulphur Dioxide and Sulphites (E220, E228) at levels > 10mg/kg or 10mg/litre	NO	NO	

Product Code: P0307

Version: 2

QMS<sup>°</sup> ISO 22000 REGISTERED

QM SV

ISO 14001





Page 4 of 12

success starts with the finest ingredients...



ADDITIVES / CONTAMINANTS / DIETARY REQUIREMENTS		Listed Item on Site at Manufacturer YES/NO	If YES, Please Comment
Additives	NO	NO	
Antioxidants	NO	NO	
Ethylene Oxide	NO	NO	
Gelatine	NO	NO	
Flavourings (Artificial / Nature Identical / Natural / Smoked)	NO	NO	
Maize / Corn and any Derivatives	YES	YES	Source Dextrose
Legumes / Pulses	NO	NO	
Rice and Rice Derivatives	NO	NO	
Added Salt	NO	NO	
Added Sugar / artificial or natural sweeteners	NO	NO	
Aspartame	NO	NO	
BHA / BHT (E320 / E321)	NO	NO	
Caffeine	NO	NO	
Colours (Artificial / Nature Identical / Natural / Smoked)	NO	NO	
Dextrose	YES	YES	Source Dextrose
Dioxins	NO	NO	
MSG (Added and Naturally Occurring E621) or Glutamates (E620 to E625)	NO	NO	
Nucleotides (E627, E630, E631, E635)	NO	NO	
Polyols (sugar alcohols)	NO	NO	
Benzoates (E210 / E219)	NO	NO	
Sorbic Acid (E200, E203)	NO	NO	
Any other Preservatives	NO	NO	
Ethanol	NO	NO	
Honey	NO	NO	
Lactose	NO	NO	
Yeast and Yeast Derivatives	NO	NO	
All Animal Products (Beef, Pork, Poultry or other) and Derivatives (which may include growth/yield hormones, antibiotics etc.)	NO	NO	
Bovine Products or Derivatives (which may include growth/yield hormones, antibiotics etc.)	NO	NO	

Product Code: P0307

Version: 2





Page 5 of 12

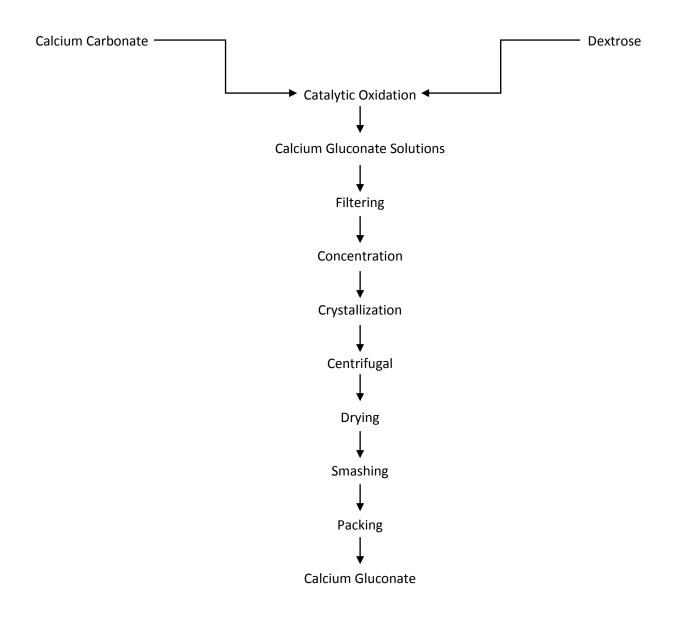
QMS<sup>°</sup> ISO 22000 REGISTERED success starts with the finest ingredients...

QM SV

ISO 14001



#### **PRODUCTION FLOW CHART**







#### **CONFIRMATION OF BSE/TSE STATUS**

This is to certify that this product complies with all relevant current UK and EU Legislative requirements in regard to Transmissible Spongiform Encephalopathies (TSE) and Bovine Spongiform Encephalopathy (BSE) for human food, and so is free of TSE/BSE.

This is also to certify that, during the course of their manufacture, the above-mentioned product did not come into contact with any materials, which could be derived from TSE/BSE risk materials.

#### **CONFIRMATION OF GM STATUS**

This is to certify that this product is not manufactured from GM raw materials and is therefore not subject to labelling under regulations 1829/2003/EC and 1830/2003/EC.

#### **CONFIRMATION OF NON IRRADIATION STATUS**

This is to certify that this product, whole or in part, has not been subjected to Ionising Radiation as per European Directives 1999/3/EC.

#### **CONFIRMATION OF NANDROLONE STATUS**

This is to certify that this product, whole or in part, has not come into contact with Nandrolone or any of its precursors in any way.

#### **CONFIRMATION OF IOC PRODUCT STATUS**

This is to certify that this product, whole or in part, has not come into contact with any product/s, which is banned by the IOC (International Olympics Committee) and or WADA.

#### **CONFIRMATION OF ANIMAL TESTING STATUS**

This is to certify that all the products sold by Cambridge Commodities have not been tested on animals in any part of its manufacture in accordance with regulation 86/609/EEC.

#### **CONFIRMATION OF PESTICIDES STATUS**

This is to certify that the above-mentioned product complies with the regulation (EC) No.396/2005 of 23rd February 2005 and commission Regulation (EU) No. 559/2011 of 7th June 2011 amending annexes II and III of the above Regulation.

#### **CONFIRMATION OF NANOPARTICLE STATUS**

This is to certify that unless otherwise stated, the above-mentioned product is free of nanoparticles. Commission Recommendation 2011/696/EU, defines as follows: "'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm".

Product Code: P0307

BRC FOOD



Version: 2

ISO 22000

QMS





Page 7 of 12

success starts with the finest ingredients...



#### **MATERIAL SAFETY DATA SHEET**

#### Section 1 Identification of the Substance/Mixture and of the Company/Undertaking

Product name: Product Code: Company:	Calcium Gluconate P0307 Cambridge Commodities Limited Lancaster Way, Ely, Cambridgeshire, CB6 3NX Tel: 01353 667258. Email: qa@c-c-l.com	
Section 2 Hazards Identification		
Potential Acute Health Effects	May be irritating to eyes, respiratory system and skin In case of contact with eyes, rinse immediately with plenty of water and seek medical advice Wear suitable protective clothing	
Potential Chronic Health Effect	Repeated or prolonged exposure is not known to aggravate medical conditions.	
Section 3 Composition/Information c	on Ingredients	
Components% in ProducCalcium Gluconate100%	t         CAS Number         Formula         EINECS Number           299 - 28 - 5         C12H22CaO14.H2O         2060 - 075 - 8	
Section 4 Emergency and First Aid Me	easures	
Eyes	Check for and remove contact lenses. In case of contact, immediately flush eye with plenty of water for at least 15 minutes.	
Skin	Cold water may be used. Get medical attention if irritation occurs. Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.	
Ingestion	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as collar, tie, belt or waistband. Get	
Inhalation	medical attention if symptoms appear. If inhaled remove to fresh air. If breathing is difficult, give oxygen and seek medical help.	

Product Code: P0307

QM SV



FEM/S

Page 8 of 12

QMS<sup>°</sup> ISO 22000 REGISTERED ISO 14001

success starts with the finest ingredients...

Registered Office: 203 Lancaster Way Business Park, Ely, Cambridgeshire, CB6 3NX, UK Registered in England No: 3590758 VAT No: GB 711 6598 32

Version: 2



#### Section 5 Fire-fighting measures

**Section 6 Accidental Release Measures** 

Flammability of The Product Product of Combustion Fire Hazard in presence	May be combustible at high temperature These products are carbon oxide (CO,CO2). Some metallic oxides.
of Various Substance	Slightly flammable in presence of heat. Non-flammable in presence of shock.
Explosion Hazard in Presence	
of Various Substances	Slightly explosive in presence of open flames and sparks. Non- explosive in presence of shock.
Extinguishing Media	Small fire- dry chemical powder. Large fire-foam, water spray, carbon dioxide. Do not use water jet.
Special Remarks on Fire Hazards	As most organic solids, fire is possible at elevated temperatures.
Special Remarks on Explosion Hazards	

Small Spill	Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the
	contaminated surface and dispose of according to local and regional authority requirements.
Large Spill	Use shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7 Handling and Storage	
Precautions	Keep away from heat. Keep away from sources of ignition. Empty
	containers pose a fire risk, evaporate the residue under a fume
	hood. Ground all equipment containing materials Do not ingest. Do
	not breathe dust. If ingested, seek medical advice immediately and
	show the container or the label. Keep away from incompatibles such as oxidizing agents.
Storage	Keep container tightly closed. Keep container in a cool, well
C C	ventilated area.

#### Section 8 Exposure Controls/Personal Protection

Engineering Controls	Use process enclosure, local exhaust ventilation, or other engineering controls to keep exposure airborne levels below recommended exposure limits. If user operation generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.				levels below n generate dust,		
Product Code: P0307			Version: 2				Page 9 of 12
BRC FOOD		ISO 14001 REGISTRED FIRM	<b>QMS°</b> ISO 22000 REGISTERED	Registered Site	FEM/S	NOS FRONTE	



**Personal Protection** 

Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

#### **Section 9 Physical and Chemical Properties**

Physical state	Solid
Colour	White/ Off White
Odour	Characteristic
Solubility	Soluble hot water. Partially soluble in cold water. Solubility in cold water: 30 g/l (20 deg.C) Solubility in hot water: 110 g/l/ (80 deg. C)
Melting Point	Decomposition temperature 100oC (212oC)
Molecular Weight	448.39 g/mole

#### Section 10 Stability and Reactivity

Chemical Stability	Stable under conditions mentioned in section 7
Hazardous Polymerisation	Product will not undergo hazardous polymerisation
Incompatibility	Reacts with oxidising agents
Conditions of Instability	Excess heat, incompatible materials

#### **Section 11 Toxicological Information**

Routes of Entry Toxicity Data Other Toxic Effects on Humans	Inhalation. Ingestion. LD50 (ORAL–RAT): >5000mg/kg Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.
Special Remarks of Toxicity to Animals	Lowest Published Lethal: LDL [Rat]- Route: Oral ; Dose: 10000 mg/kg LDL [Mouse]- Route: Oral; Dose: 10000 mg/kg
Special Remarks on other Toxic Effects	on Humans
Acute potential Health Effects	<ul> <li>Skin: May cause skin irritation. Eyes: May cause eye irritation.</li> <li>Inhalation: May cause respiratory tract irritation.</li> <li>Ingestion: Ingestion of large amounts may cause gastrointestinal tract irritation with nausea. It may affect respiration (dyspnea, cyanosis), and heart (ventricular fibrillation).</li> <li>Other symptoms may include weakness, depression, and prostration. It is expected to be low ingestion hazard.</li> </ul>

#### **Section 12 Ecological Information**

Eco-toxicity
Products of Biodegradation

No Data Available Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Product Code: P0307

Version: 2

QMS





Page 10 of 12

success starts with the finest ingredients...



Waste must be disposed of in accordance with federal, state and local environmental control regulation.
Not D.O.T. controlled material (United States)
No product found WHMIS (Canada)- Not controlled under WHMIS (Canada) DSCL (EEC)- This product is not classified according to the EU regulations. S24/25- Avoid contact with skin and eyes. HMIS (U.S.A)- Health Hazard:1, Fire Hazard:1, Reactivity:0, Personal Protection: E National Fire Protection Association (U.S.A)- Health:1, Flammability: 1, Reactivity:0
Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Safety glasses.
s Health & Safety at work act 1974 COSHH Regulations (1994) EH40 Occupational exposure limits Not known

#### **Section 16 Other Information**

This advice is given by Cambridge Commodities Ltd who accepts no legal liability for it. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

Individuals working with chemicals should consider all chemicals to be potentially hazardous even if their individual hazards may be uncharacterised or unknown.

This Information provided in this document is subject to change and the batch specific Certificate of Analysis should always be referenced.

To be used as per local legislation.

Product Code: P0307



Version: 2

QMS





Page 11 of 12

success starts with the finest ingredients...

ISO 22000



#### **Change History**

Version	Change	Customer Notification required Yes / No
1	First Issue	N/A
2	<ul> <li>The following has been updated due to the supplier updating their specifications:</li> <li>Sieve analysis, Magnesium &amp; Alkali Metals, Phosphate, Oxalate, Bacterial Endotoxins removed.</li> <li>Shelf Life from Date of Manufacture changed from 3 years to Min 2 Years</li> <li>Chloride changed from Max 50ppm to max 0.07%</li> <li>Sulphate changed from Max 50ppm to max 0.05%</li> <li>Yeast &amp; Moulds added</li> <li>Heavy metals added</li> </ul>	Yes

#### **Document Approval**

Originator Job Title	QC Technician	Approver Job Title	QC Technician
Jennifer Fordham (Feb 22, 20	)16)	<u>Adam Hulcahy</u> Adam Mulcahy (Feb 22, 2016)	

Product Code: P0307

Version: 2

QMS<sup>°</sup> ISO 22000 REGISTERED

QM SV

ISO 14001





Page 12 of 12

success starts with the finest ingredients...



# P0307 -Calcium Gluconate-Technical Dossier

nt Cloud Document 2/22/16	
2/22/16	
Adam Mulcahy (adam.mulcahy@c-c-l.com)	
SIGNED	
CBJCHBCAABAAqXrtX5f7dWpNS-uPkq10Czd01-mIV7tw	

## "P0307 - Calcium Gluconate- Technical Dossier" History

- Document uploaded by Adam Mulcahy (adam.mulcahy@c-c-l.com) from Reader 2/22/16 - 8:42:19 PST - IP address: 81.145.42.226
- Document signed in Reader by Adam Mulcahy (adam.mulcahy@c-c-l.com) Signature Date: 2/22/16 - 8:44:38 PST - Time Source: server - IP address: 81.145.42.226
- Document emailed to Jennifer Fordham (jennifer.fordham@c-c-l.com) for signature 2/22/16 8:44:45 PST
- Document viewed by Jennifer Fordham (jennifer.fordham@c-c-l.com) 2/22/16 - 8:45:48 PST - IP address: 81.145.42.226
- Document e-signed by Jennifer Fordham (jennifer.fordham@c-c-l.com) Signature Date: 2/22/16 - 8:46:06 PST - Time Source: server - IP address: 81.145.42.226
- Signed document emailed to Adam Mulcahy (adam.mulcahy@c-c-l.com) and Jennifer Fordham (jennifer.fordham@c-c-l.com) 2/22/16 - 8:46:06 PST