



גדות תעשיות ביוכימיה בע"מ  
Gadot Biochemical Industries Ltd.

# Tri Calcium Citrate

## Tetrahydrate FCC/USP

## Tableting Grade

### General Characteristics:

|                          |   |
|--------------------------|---|
| <b>Formula:</b>          | $\text{Ca}_3(\text{C}_6\text{H}_5\text{O}_7)_2 \cdot 4\text{H}_2\text{O}$ |
| <b>Molecular weight:</b> | 570.5   |
| <b>Appearance:</b>       | Fine white free flowing powder  |
| <b>Odor:</b>             | Odorless  |
| <b>Solubility:</b>       | In water - Almost insoluble<br>In alcohol - Insoluble                     |
| <b>CAS Number:</b>       | 5785-44-4   |
| <b>E-Number:</b>         | E-333   |

### Standard Specifications:

Gadot's Tri Calcium Citrate Tetrahydrate meets the standards of the Food Chemical Codex, the United States Pharmacopoeia, and FAO/WHO JECFA. The product complies with the European directive EC 231/2012 in the latest version.

|                                  |                        |
|----------------------------------|------------------------|
| Identification                   | Meets FCC/USP tests    |
| Loss on drying (4 hrs. at 150°C) | 10-13%                 |
| Assay (dry basis)                | 97.5-100.5%            |
| Assay as Ca (dry basis)          | 23.5-24.2%             |
| Assay as Ca (as is)              | 20.4 – 21.8%           |
| Heavy metals (as Pb)             | 5 ppm max.             |
| Nitrite and Nitrate              | non detectible         |
| Lead                             | Less than 0.2 ppm max. |
| Arsenic (as As)                  | 0.5 ppm max.           |
| Fluoride (as F)                  | 30 ppm max.            |
| Aluminum                         | 30 ppm max.            |
| Acid insoluble substances        | 0.2% max.              |
| pH (5%)                          | 4.5-7.8                |
| Bulk density                     | 700 g/l min.           |
| Mercury                          | 0.1 ppm max.           |
| Cadmium                          | 0.5 ppm max.           |
| Carbonate                        | Passes test            |



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### Organic Volatile Impurities

Gadot' Tri Calcium Citrate Tetrahydrate contains no tridodecylamin nor any polynuclear hydrocarbons or volatile organic impurities. These compounds are not used in the manufacturing process of the above product and if tested they will comply with the required specified limits of U.S.P

| <u>Impurities</u>    | <u>Limit</u> |
|----------------------|--------------|
| Benzene              | 2 PPM        |
| Carbon tetrachloride | 4 PPM        |
| 1,2 - Dichloroethane | 5 PPM        |
| 1,1 – Dichloroethene | 8 PPM        |
| Chloroform           | 60 PPM       |
| 1,4 - Dioxane        | 380 PPM      |
| Ethylen Oxide        | 10 PPM       |
| Methylen Chloride    | 600 PPM      |
| Tri Chloroethylene   | 80 PPM       |

### Nutritional Values:

| <u>Nutrient</u>   | <u>Nutrient Quantity</u>                    |
|-------------------|---|
| Protein           | - none                                      |
| Carbohydrates     | - none                                      |
| Fat               | - none                                      |
| Vitamin A         | - none                                      |
| Vitamin C         | - none                                      |
| Thiamin           | - none                                      |
| Riboflavin        | - none                                      |
| Niacin            | - none                                      |
| Calcium           | - 20.4 – 21.8%                              |
| Vitamin D         | - none                                      |
| Vitamin B-6       | - none                                      |
| Vitamin B-12      | - none                                      |
| Heavy metals      | - 5 ppm max.                                |
| Lead              | - 0.3 ppm max.                              |
| Fluoride          | - 30 ppm max.                               |
| Caloric Value     | - 163 Kcal/100 gr.                          |
| Artificial colors | - product does not contain artificial color |

### Allergens:

Gadot's Tri Calcium Citrate, doesn't contain any food allergens according to annex 3a of EU directive 2003/89.



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### Standard Granulation:

|             |       |              |          |
|-------------|-------|--------------|----------|
| On No.      | 40 -  | 425 micron - | 0%       |
| On No.      | 60 -  | 250 micron - | 50% min. |
| Through No. | 120 - | 125 micron - | 15% max. |

Particle size distribution is analyzed by Laser diffraction after ultrasonic treatment of sample.

### Other requirements:

Foreign Bodies: In compliance with the FDA/ORA compliance policy guide section 555.425.

### BSE/TSE

No raw materials from bovine origin are used nor are any bovine constituents present in the product.

### Hormones and Antibiotics

No antibiotics or hormones are present in the product.

### Mycotoxines:

|                   |                  |     |
|-------------------|------------------|-----|
| Total Aflatoxines | - less than 4    | ppb |
| Aflatoxins B1     | - less than 2    | ppb |
| Aflatoxins M1     | - less than 0.05 | ppb |

### Pesticides and Insecticides:

Complies with United States and European food health regulations.

### GMO - Status:

The product is a non GMO product and is free from any recombinant DNA technology involvement.



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### **Irradiation / Radioactivity:**

Gadot's Tri Calcium Citrate was never subjected to any kind of ionized irradiation and contains no radioactivity not even in minor amounts.

### **Microbiological Specification:**

|                        |   |                  |
|------------------------|---|------------------|
| Total viable count     | - | 500 CFU/gr. max. |
| Yeast & Molds          | - | 20 CFU/gr. max.  |
| E. Coli                | - | Absent in 10 gr. |
| Staphylococcus Aureus  | - | Absent in 10 gr. |
| Pseudomonas Aeruginosa | - | Absent in 10 gr. |
| Salmonella             | - | Absent in 25 gr. |
| Coliforms              | - | 10 CFU/gr. max.  |
| Listeria Monocytogenes | - | Absent in 25 gr. |

### **Main Uses:**

- Calcium fortification food.
- Dietary supplements.
- Acidity regulator in food.
- Firming agent.
- Not for use in the preparation of injectable solutions.

### **Packaging:**

50 Lbs or 25 Kg. polyethylene lined cartons.

All packaging materials used are suitable for food applications according to FDA and EU regulations.

### **Expiry Date:**

Tri Calcium Citrate Tetrahydrate has a shelf life of two years from production date. The production date is printed on the bags.

### **Kosher:**

Tri Calcium Citrate Tetrahydrate produced by Gadot is strictly Kosher and Halal. Certificates are available upon request.



## גדות תעשיות ביוכימיה בע"מ Gadot Biochemical Industries Ltd.

### Vegetarians / Vegans:

Tri Calcium Citrate produced by Gadot is suitable for consumption by vegetarians and vegans.

### ISO 9000:

Gadot is ISO-9001 : 2008 certified.

### HACCP:

Gadot Biochemical Industries Ltd. Food Safety Management System - HACCP comply with:

1. CODEX ALIMENTARIUS – Annex to CRC/RCP – 1969 Rev.3 (1997).
2. Health Ministry Guide for HACCP, March 2002 Edition.

### GMP:

Gadot Biochemical Industries is GMP certified.

Gadot manufacture its Tri Calcium Citrate Tetrahydrate under strict supervision and full compliance with all GMP rules, and therefore permitted to label it's product with official GMP symbol as laid down in the public health regulations.

### Storage Recommendations:

Store in a cool, dry place.

Updated: December 3<sup>rd</sup>, 2015