



גדות תעשיות ביוכימיה בע"מ
Gadot Biochemical Industries Ltd.

Tri Calcium Citrate

Tetrahydrate FCC/USP

General Characteristics:

Formula:	$\text{Ca}_3(\text{C}_6\text{H}_5\text{O}_7)_2 \cdot 4\text{H}_2\text{O}$
Molecular weight:	570.6
Appearance:	Fine white free flowing powder
Odor:	Odorless
Solubility:	In water - Almost insoluble In alcohol - Insoluble
CAS Number:	5785-44-4
EINECS No.:	212-391-7
E-Number:	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
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
Mercury	0.1 ppm max.
Cadmium	0.5 ppm max.
Oxalate	100 ppm max.
Carbonate	Passes test
Bulk Density (untapped)	650 gr/l min.
Manganese	50 ppm max.



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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	- 0.2 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 and directive 2007/68/ES.



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Standard Granulation:

<u>M2:</u>	97% less than 10 micron d(10) = 0.9 micron typical
<u>M5:</u>	97% less than 30 micron d(10) = 1.15 micron typical
<u>M8:</u>	97% in range 60 - 70 micron
<u>M30:</u>	d(10) = 1.6 micron min. d(50) = 20-30 micron d(90) = 78 micron max.
<u>HD:</u>	d(10) = 43 micron typical d(50) = 73 micron typical d(90) = 120 micron typical

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

Other requirements:

Foreign Bodies : No foreign bodies that can be monitored by our HACCP plan will be found in the product (for details please refer to our CCP tables for this production plant)

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.



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GMO - Status:

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

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/ 10 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 lb, 20 Kg. or 10 Kg. polyethylene-lined multi-wall paper bags, palletized and stretch-wrapped. Big bags and other packaging available on request.
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.



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Kosher:

Tri Calcium Citrate Tetrahydrate produced by Gadot is strictly Kosher. Kosher certificates are available upon request.

Vegetarians / Vegans:

Tri Calcium Citrate Tetrahydrate 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, 2015