



גדות תעשיות ביוכימיה בע"מ
Gadot Biochemical Industries Ltd.

Tri Calcium Phosphate FCC/NF/EP

General Characteristics:

Formula:	Ca ₅ (PO ₄) ₃ (OH)
Molecular weight:	502
Appearance:	White free flowing powder. (For Granulated Grade – white granules)
Taste:	Tasteless
Odor:	Odorless
Solubility:	In water - Almost insoluble In alcohol - Insoluble
CAS Number:	7758-87-4 12167-74-7 1306-06-5
EINECS No.:	231-840-8
E-Number:	E-341

Standard Specifications:

Gadot's Tri Calcium Phosphate meets the standards of the Food Chemical Codex, the National Formulary (NF), the European Pharmacopoeia and FAO/WHO JECFA. The product complies with the European directive EC 231/2012 in the latest version.

Identification	Meets FCC/NF/EP tests
Assay (as Ca)	35-40%
Loss on ignition (800°)	8% max.
Heavy metals (as Pb)	5 ppm max.
Nitrite and Nitrate	non detectible
Lead (as Pb)	0.5 ppm max.
Fluoride (as F)	50 ppm max.
Arsenic (as As)	0.5 ppm max.
Acid insoluble substances	0.1% max.
Water soluble substance	0.5% max.
Titration Value	13-14.3
Sulphate	0.5% max.
Chlorides	0.14% max.
Carbonate	passes test
Iron	400 ppm max.
Cadmium	0.5 ppm max.
Mercury	0.1 ppm max.
Barium	Passes test
Aluminum*	200 ppm max.
pH	5.0 – 7.5

* Product with upper spec limit of 150 ppm is available upon request.



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Organic Volatile Impurities

Gadot's Tri Calcium Phosphate 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 and E.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 (dairy derived)	- None
Carbohydrates	- None
Calcium	- 35 – 40%
Phosphate	- 56.6 – 62.6%
Fat	- None
Vitamin A	- None
Vitamin C	- None
Thiamin	- None
Riboflavin	- None
Niacin	- None
Lead	- < 0.5 ppm
Iron	- 50- 80 ppm Typical
Vitamin D	- None
Vitamin B-6	- None
Vitamin B-12	- None
Fluoride	- < 50 ppm
Magnesium	- 0.2% max.
Sodium	- 0.2% max.
Zinc	- None
Pantotenic Acid	- None
Artificial colors	- product does not contain artificial color
Caloric value	- None



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Allergens:

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

Standard Granulation:

+ L.D.	d(90)	25 micron max.
+ H.D.	d(90)	60 micron max.
	d(97)	80 micron max.
M-3	d(50)	2-4 micron
Granulated:	On 40 US Mesh	5% max
	Through 100 US Mesh	10 % max

Particle size distribution is analyzed by Laser diffraction after ultrasonic treatment of sample. For Granulated grade the test performed by sieves.

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.



Irradiation / Radioactivity:

Gadot's Tri Calcium Phosphate 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	-	Less than 10 CFU/10gr.
Molds	-	Less than 10 CFU/10gr. max.
E. Coli	-	Absent in 1 gr.
Staphylococcus Aureus	-	Absent in 1 gr.
Pseudomonas Aeruginosa	-	Absent in 1 gr.
Salmonella	-	Absent in 25 gr.
Coliforms	-	less than 10 CFU/gr. max.
Listeria Monocytogene	-	Absent in 25 gr.
Total Mesophilic spores	-	less than 10 CFU/gr. Max
Total Thermophilic spores	-	less than 10 CFU/gr. Max

Bulk Densities:

<u>Grade</u>	<u>Bulk Densities</u>
H.D (g/ml)	0.3 – 0.5
L.D (g/ml)	< 0.3
M-3	Not defined
Granulated	Not defined

Main Uses:

- Food fortification.
- Free flowing agent for powdered products such as icing sugar, flours and dry bases for soups and drinks.
- Dispersant in tablet manufacture.
- Polymerization of styrene.
- Ceramic coloring agent.
- Not for use in the preparation of injectable solutions.

Packaging:

25 Kg. or 50 lb polyethylene-lined multi-wall paper bags for the HD fraction.

20 Kg. or 50 lb polyethylene-lined multi-wall paper bags for the LD fraction.

10 Kg. polyethylene-lined multi-wall paper bags for the M-3 fraction.

Bags are 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.



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Expiry Date:

Tri Calcium Phosphate has a shelf life of two years from production date. The production date is printed on the bags, therefore, the expiry date can be figured out.

Kosher:

Tri Calcium Phosphate produced by Gadot is strictly Kosher. Kosher certificates available upon request.

Vegetarians / Vegans:

Tri Calcium Phosphate 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 Phosphate 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 3rd , 2015