



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