



גדות תעשיות ביוכימיה בע"מ
Gadot Biochemical Industries Ltd.

Tri Sodium Citrate Dihydrate FCC/USP/BP/EP

Description:

Tri Sodium Citrate Dihydrate is a white crystalline product.

General Characteristics:

Formula:	$C_6H_5Na_3O_7 \cdot 2H_2O$
Molecular weight:	294.11
Appearance:	White crystals
Taste:	Saline taste
Odor:	Practically odorless
Solubility (gr/100 ml at 25°C)	In water: 71 In ethanol: Insoluble
CAS Number:	61-32-04-3
EINECS No.:	200-675-3
E-Number:	E-331

Standard Specifications:

Gadot's Tri Sodium Citrate Dihydrate meets the standards of the Food Chemical Codex, the United States Pharmacopoeia, the British Pharmacopoeia and the European Pharmacopoeia. The product complies with the European directive EC 231/2012 in the latest version.

Identification	Meets FCC/USP/EP/BP tests
Assay (anhydrous basis)	99.0% - 100.5%
Loss on drying (180°C 18 Hrs)	11.0 – 13.0%
Alkalinity	passes test
Tartrate	passes test
Readily carbonizable substances	Passes test
Heavy metals (as Pb)	5 ppm max.
Arsenic (as As)	0.5 ppm max.
pH (1%)	7.5 – 9.0
Bulk density	750 – 1,150 gr/Lit
Color	Passes test
Oxalates	100 ppm max.
Chloride	50 ppm max.
Sulfates	100 ppm max.
Lead	0.5 ppm max.
Iron	5 ppm max.
Color of solution (40% w/v)	98% min.(% T in 420 nm)
Clarity of solution (40% w/v)	4 NTU max.
Mercury	0.1 ppm max.
Cadmium	0.5 ppm max.



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Organic Volatile Impurities

Gadot's Tri Sodium Citrate Dihydrate 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
Fat	- None
Sodium	- 23.2 – 23.6%
Vitamin A	- None
Vitamin C	- None
Thiamin	- None
Riboflavin	- None
Niacin	- None
Calcium	- 30 mg/kg
Iron	- < 5 mg/kg
Vitamin D	- None
Vitamin B-6	- None
Vitamin B-12	- None
Phosphorus	- None
Magnesium	- < 1 mg/kg
Zinc	- None
Pantotenic Acid	- None
Potassium	- 500 mg./kg
Artificial colors	- product does not contain artificial color
Caloric value	- 180 Kcal/100 gr.



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Allergens:

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

Standard Granulation:

Grade	USS Sieve	Microns	
Regular Granular	On No. 16	> 1190	5% max.
	Through No. 100	< 150	10% max.
Standard Granular	On No. 16	> 1190	5% max.
	Through No. 50	< 300	10% max.
Fine Granular	On No. 30	> 590	5% max.
	Through No. 100	< 150	10% max.

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.



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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 Sodium Citrate Dihydrate 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:

- Adjusts pH control (in combination with Citric Acid) in the food, beverage and pharmaceutical industries.
- Used as an anticoagulant agent in meat industry.
- Stabilizes emulsified fat, complexes calcium ions in cheese industry.
- Tri Sodium Citrate Dihydrate is a bio-degradable detergent builder.
- Not for use in the preparation of injectable solutions.

Packaging:

25 kg. or 50 lb. 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 Sodium Citrate Dihydrate has a shelf life of two years from production date. The production date is printed on the bags.



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Kosher:

Tri Sodium Citrate Dihydrate produced by Gadot is strictly Kosher. Kosher certificates are available upon request.

Vegetarians / Vegans:

Tri Sodium Citrate Dihydrate 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 Sodium Citrate Dihydrate 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 and dry place.

Updated: December 3rd, 2015