



SAFETY DATA SHEET

Tri Calcium diCitrate Anhydrous

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Complying with 1907/2006/EEC Regulation of 18 December 2006 ("REACH Regulation") and REGULATION (EC) No 1272/2008 (CLP)

Section 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Identification of the substance/preparation

Product name: Tri Calcium diCitrate Anhydrous

Chemical name (e.g. IUPAC name): Tri Calcium diCitrate Anhydrous

Trade names: Tricalcium dicitrateterahydrate

Synonyms: Tricalcium dicitrateterahydrate

Use of the substance/preparation:

Calcium fortification food. Dietary supplements. Acidity regulator in food. Firming agent.

Company/undertaking identification

Supplier/Manufacturer: Gadot Biochemical Industries Ltd 117 Hahistadrut Ave P.O.B 10636 Haifa Bay 26118 Israel

Tel: +972-4-8461555 Fax: +972-4-8461560

E-mail address of person responsible for this SDS:

Nissim Guigui - R&D and Quality Manager nissim@gadotbio.com

Emergency telephone number (with hours of operation): +972-4-8461555

Section 2. HAZARDS IDENTIFICATION

According to EC Directive 2001/59/EC Most Important Hazards Not classified

Classification Not required

GHS-Classification Hazards Statements Not classified

Signal Word Not required

See section 11 for more detailed information on health effects and symptoms.





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Section 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance/preparation:

Chemical name: Tri Calcium diCitrate Anhydrous

Formula: $Ca_3(C_6H_5O_7)_2*4H_2O$ Molecular weigth: 570,49 g/mol

Ingredient name	CAS number	%	EC number	EU Classification	GHS Classification
Tri Calcium diCitrate Anhydrous	813-94-5	100%		-	-
See section 16 for the full text of the R-phrases declared above					

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in section 8.

Section 4. FIRST AID MEASURES

Eyes contact:	Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention immediately if irritation develops or persists or if visual changes occur.
Skin contact:	In case of contact, immediately wash with soap and plenty of water. Get medical attention if irritation develops or persists. Remove contaminated clothing and shoes. Clean contaminated clothing and shoes before re-use.
Inhalation:	If respiratory irritation or distress occurs, remove victim to fresh air. Get medical attention if respiratory irritation or distress continues.
Ingestion:	If victim conscious and alert, give 2-3 glasses of water to drink. DO NOT INDUCE VOMITING. Do not give anything by mouth to an unconscious person. Get medical attention.

Expected delayed effects: N/A

See section 11 for more detailed information on health effects and symptoms.



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Section 5: Fire-Fighting Measures

Extinguishing media

Suitable: Water spray, foam, dry chemical or carbon dioxide.

Not suitable: N/A

Special exposure hazards arising from the substance/preparation including combustion products and gases: Under fire emits calcium, calcium oxides and irritating and toxic fumes.

Special protective equipment for fire fighters: Fire fighters should wear full protective clothing and self-contained breathing apparatus in positive pressure mode.

Further information: Move containers from fire area if possible to do so without risk.

Section 6: Accidental Release Measures

Personal precautions: Wear protective clothing. Avoid contact with skin eyes and inhalation of dust. Remove all sources of ignition. Ventilate area of spill. Avoid dust formation.

Environmental precautions: Prevent entry into waterways, sewers, basements or confined areas.

Methods for cleaning up

<u>Small spill:</u> Pick up and place in a suitable container for reclamation or disposal, using a method that does not generate dust.

Large spill: As for small spill.

Section 7: Handling and Storage

Handling: Avoid contact with eyes, skin and clothing. Do not permit eating/drinking/smoking near the material. Keep away from heat, sparks and open flame. Avoid raising dust.

Storage: Keep containers tightly closed, in dry, cool and well-ventilated place. Do not store together with strong oxidizing agents. Protect from humidity.

Section 8: Exposure Control / Personal Protection

Exposure limit values: N/A

Exposure controls

Occupational exposure controls: Use process enclosures, local exhaust ventilation, or others engineering controls to keep airborne levels below recommend exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.



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<u>Respiratory protection</u>: Dust mask. Be sure to use an approved/certified or equivalent. Wear appropriate respirator when ventilation is inadequate.

Hand protection: Chemically compatible gloves.

Eye protection: Wear protective safety goggles.

Skin protection: Wear appropriate long-sleeved clothing to minimize skin contact.

Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Section 9: Physical and Chemical Properties

General information Physical state: Powder Color: White Odor: No unusual odor

Safety data

pH: 5-8 (5% slurry) Boiling point/boiling range: N/A Flash point: N/A Flammability (solid, gas): N/A Explosive properties: Bureau of Mines Relative Hazard Rating: no explosion detected up to 200 g/ft3 air. Oxidizing properties: N/A Vapor pressure: N/A Water solubility: Practically zero Relative density: N/A Solubility: N/A Octanol/Water partition coefficient: N/A Viscosity: N/A Vapor density: N/A Evaporation rate (butyl acetate=1): N/A

Other information:

Melting point/melting range: N/A Auto-ignition temperature: N/A

Section 10: Stability and Reactivity

Stability: The product is stable under normal handling and storage conditions described in Section 7.

Conditions to avoid: Keep away from heat, sparks and open flame. Protect from humidity.

Materials to avoid: Strong oxidizing agents.

Hazardous Decomposition products: Under fire- Calcium oxides, irritating and toxic fumes.



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Hazard polymerization: N/A

Section 11: Toxicological Information

Potential acute health effects

Acute toxicity: N/A

Irritation and corrosivity:

Inhalation: May cause coughing, sneezing and labored breathing.

Ingestion: Large quantities may cause nausea, vomiting and cramps.

Skin contact: May cause skin irritation. May be harmful by skin absorption.

Eves contact: May cause eyes irritation.

Sensitization: N/A

CMR Effects

<u>Carcinogenicity</u>: Citric acid: In a rat feeding study, animals dosed with 5% citric acid in the diet did show an excess of tumours in comparison with control animals when tested over a period of 2 years. However, there was some evidence that high doses of citrate salts potentiated the incidence of tumours produced by co-administration of known bladder carcinogens. Where citric acid or citrate salts were administered alone during these studies, no dose-related tumours were noted.

It is not expected that sodium, calcium, potassium or magnesium counter ions will contribute significantly to the genetic toxicity of their corresponding salts. Therefore, it is possible to reliably read-across from citric acid to the other citrate salts in this category.

Mutagenicity: Citric acid has been tested in a number of bacterial assays, all of which gave negative results. There is information from a lower reliability study that citric acid and sodium dihydrogen citrate do not cause chromosome aberrations *in vitro*: this result does not agree with a recently published study. Evidence for genetic toxicity has been described in a recent publication of results from an *in vitro*. An *in vivo* chromosome aberration study does not support the conclusion of the recently reported *in vitro* studies in mammalian cells, and an *in vivo* rodent dominant lethal assay also showed no evidence of chromosome damage, so it is considered that the *in vitro* results do not reflect a potential for genetic toxicity.

Citric acid is negative in *in vivo* genotoxicity testing, although effects have been observed in some *in vitro* studies. Moreover, it has been used as a food additive over a long period. In addition, citrate plays a central role in cellular metabolism, so it is considered that classification for mutagenicity is not required. Information available in the public domain on tests carried out on other salts of sodium, calcium, potassium and magnesium indicates that the metal ions are not expected to contribute to the genetic toxicity of their corresponding salts. Therefore, information from citric acid may be read-across to the other citrate salts in this category, and information may be read-across between the citrate salts, and classification of the citrate salts in the category for mutagenicity is not required.



It is not expected that sodium, calcium, potassium or magnesium counter ions will contribute significantly to the genetic toxicity of their corresponding salts. Therefore, information from citric acid may be readacross to the other citrate salts in this category, and information may be read-across between the citrate salts, and classification of the citrate salts in the category for mutagenicity is not required.

Reproductive toxicity: Citric acid: various studies on rats, mice and guinea pigs using a number of different conditions and protocols: prior to mating, during pregnancy and also a two-generation study were summarised in the OECD report. In some the doses were defined and in others the regimen was *ad libitum* feeding of a defined concentration of citric acid in the diet, with or without measurement of food uptake. No adverse effects on females or foetuses were reported except slight dental attrition of the females in some of the studies. The NOEL values reported were often meaningless as it was the only dose used, and that gave no adverse effects. In the same report described above, Wright and Hughes (1976c) showed the same dose (5%) of citric acid in the diet of female mice and rats had no effect on the reproductive performance as measured by pregnancy rate, number of live births, still births and pup survival rate.

It is not expected that sodium, calcium, potassium or magnesium counter ions will contribute significantly to the genetic toxicity of their corresponding salts. Therefore, it is possible to reliably read-across from citric acid to the other citrate salts in this category.

Other effects

Over exposure signs/symptoms: N/A

Section 12: Ecological Information

Ecotoxicity: N/A

Mobility: N/A

Persistence and Degradability: N/A

Bioaccumulative potential: N/A

Result of PBT assessment (if CSR is required): N/A

Other adverse effects:

Substances which have an unfavorable influence on the oxygen balance and can be measured using parameters such as BOD, COD, etc.: N/A

Substances, which contribute to eutrophication: N/A

Remarks: N/A



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Section 13: Disposal Considerations

Methods of disposal: Waste must disposed of in accordance with federal, state and local environmental control regulations.

Hazardous waste: N/A

Section 14: Transport Information

International transport regulations: Not regulated by ADR/RID, IMDG or IATA.

National Fire Protection Association Hazard Ratings- NFPA (R):

- 1 Health Hazard Rating Moderate
- 0 Flammability Rating Slight
- **0** Instability Rating Minimal

Section 15: Regulatory Information

Classification and labeling according to EU Directives 67/548/EEC and 1999/45/EC (including amendments) and take into account the intended product use:

Labelling in accordance with EC directives: No symbol required

Risk phrases: Not classified

Safety phrases: Not required

Classification and labeling according to EU Regulation (EC) 1272/2008 (CLP Regulation) and Globally Harmonized System (GHS):

Signal Word: Not required

Hazards Statements: Not classified

Precautionary Statements: Not required

National Paint & Coating Hazardous Materials Identification System - HMIS (R):

- 1 Health Hazard Rating -Slight
- 0 Flammability Rating Minimal
- 0 Instability Rating Minimal
- A Personal Protection



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Section 16: Other Information

Full text of R-phrases referred to in sections 2 and 3: N/A

Full text of Hazards Statements referred to in sections 2 and 3: N/A

Training advice: Before using/handling the product one must read carefully present MSDS.

Recommended restriction: N/A

Key Legend Information: ACGIH- American Conference of Governmental Industrial Hygienists OSHA- Occupational Safety and Health Administration NTP- National Toxicology program IARC- International Agency for Research on Cancer ND- Not Determined N/A- Not available R-phrases- Risk phrases S-phrases- Safety phrases

Date of issue: 24th November 2010 Version no. 1

According to Regulation (EC) No. 1907/2006 (REACH), Annex II, Commission Directive 2001/59/EC and REGULATION (EC) No 1272/2008 (CLP).

To the best of our knowledge the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.