

Tri Calcium diCitrate Tetrahydrate

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Complying with 1907/2006/EEC Regulation of 18 December 2006 ("REACH Regulation")

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name: Tri Calcium diCitrate Tetrahydrate

CAS: 5785-44-4

Formula: Ca₃(C₆H₅O₇)₂·4H₂O

Synonyms: Tricalcium dicitrateterahydrate; TCC;

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses:

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

Firming agent.

1.3 Details of the supplier of the safety data sheet

Gadot Biochemical Industries Ltd. 117-119 Hahistadrut Rd. POB 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

1.4 Emergency telephone number

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification in accordance to Regulation (EC) No. 1272/2008 (CLP): Not classified

2.2 Label elements

Labelling in accordance with Regulation 1272/2008 (CLP)

Hazard pictogram(s): Not required

Signal word: Not required

Hazard statement(s): Not required

Precautionary Statement(s): Not required

2.3 Other hazard

Not available



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SECTION 3: Composition/information on ingredients

3.1 Substances:

Substance name	Identifiers	%	CLP Classification
Tri Calcium diCitrate Tetrahydrate	CAS number: 5785-44-4 EC number: N/A	100	Not classified

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

4.1 Description of first aid measures

Eyes contact: In case of contact with eyes, rinse immediately with plenty of water for at least 15

minutes. Get medical attention.

Skin contact: Take off contaminated clothing and shoes immediately. Wash off with soap and plenty

of water. Get medical attention.

Inhalation: Remove the victim from site of exposure to fresh air. If breathing is difficult, give

oxygen. If not breathing give artificial respiration. Get medical attention.

Ingestion: Do not induce vomiting. If victim is conscious, wash mouth thoroughly with plenty of

water. Never give anything by mouth to an unconscious person. Get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See section 2.2 (Label elements) and/or section 11 (Toxicological information) for the most important known symptoms and effects.

4.3 Indication of any immediate medical attention and special treatment needed

Not available

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

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

Not suitable: N/A

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: Under fire emits calcium, calcium oxides and irritating and toxic fumes.

5.3 Advice for firefighters

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



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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Ventilate area of spill. Avoid dust formation.

6.2 Environmental precautions

Prevent entry into waterways, sewers, basements or confined areas.

6.3 Methods and materials for containment and cleaning up

Pick up and place in a suitable container for reclamation or disposal, using a method that does not generate dust.

6.4 Reference to other sections

See Section 1 for emergency contact information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid inhalation of vapors, mist or gas. Wash thoroughly after handling. Keep away from heat, sparks and open flame. Avoid dust formation. Handle in accordance with good industrial hygiene and safety practice.

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also section 8 for additional information measures.

7.2 Conditions for safe storage, including any incompatibilities

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

7.3 Specific end use(s): N/A

SECTION 8: Exposure control/personal protection

8.1 Control parameters

Not available.

8.2 Exposure controls

Engineering measures

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.

Person Protective measures

Respiratory protection: Disposable particulate mask. Be sure to use an approved/certified equipment or equivalent equipment. Wear appropriate respirator when ventilation is inadequate.

Hand protection: Wear protective gloves to prevent skin exposure.

Eye protection: Wear protective safety glasses.

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



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Environmental exposure controls: Not available

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: White powder Odour: No unusual odor Odour threshold: N/A pH: 5-8 (5% slurry)

Melting point/Freezing point: N/A Initial boiling point/boiling range: N/A

Flash point: N/A Evaporation rate: N/A Flammability: N/A

Upper/lower flammability or explosive limits: N/A

Vapor pressure: N/A Vapor density: N/A Relative Density: N/A

Solubility(ies): Practically zero in water Partition coefficient Octanol/Water: N/A

Auto-ignition temperature: N/A Decomposition temperature: N/A

Viscosity: N/A

Explosive properties: Bureau of Mines Relative Hazard Rating: no explosion detected up to 200 g/ft3 air.

Oxidizing properties: N/A

9.2 Other information

Formula: Ca₃(C₆H₅O₇)₂·4H₂O Molecular weigth: 570.49 g/mol

SECTION 10: Stability and reactivity

10.1 Reactivity

Not available

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Hazardous reactions are not expected, under normal conditions of storage and use.

10.4 Conditions to avoid

Heat, sparks and open flame. Humidity.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

Other decomposition products: not available.

In the event of fire: see section 5.



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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity: N/A

Skin corrosion/irritation: N/A

Serious eye damage/irritation: N/A

Respiratory or skin sensitization: N/A

Germ cell 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.

Carcinogenicity:

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 coadministration 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.

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



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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 symptoms:

May cause skin irritation. May be harmful by skin absorption.

May cause eye irritation.

May cause coughing, sneezing and labored breathing.

SECTION 12: Ecological information

12.1 Toxicity

Not available

12.2 Persistence and Degradability

Not available

12.3 Bioaccumulative potential

Not available

12.4 Mobility in soil

Not available

12.5 Results of PBT and vPvB assessment

Not available

12.6 Other adverse effects

Not available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

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

Packing

Empty containers should be taken for local recycling, recovery or waste disposal.



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SECTION 14: Transport information

14.1 Un number

ADR/RID: - IMDG: - IATA: -

14.2 Proper shipping name

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ADR/RID: Not regulated

IMDG: Not regulated

IATA: Not regulated

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packing group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazard

Marine Pollutant: N/A

14.6 Special precautions for user

Not available

Additional information

ADR/RID: - IMDG: - IATA: -

14.7 Transport to bulk according to Annex II of MARPOL 79/78 and the IBC Code

Not available

SECTION 15: Regulatory information

This SDS complies with the following requirements of: EU Directives 67/548/EEC (DSD) and 1999/45/EC (DPD), including amendments EU Regulation (EC) No.1907/2006 (REACH) including amendments Regulation (EC) No.1272/2008 (CLP)

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Not available

15.2 Chemical safety assessment

Not available

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SECTION 16: Other information

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

Key Legend Information:

CAS - Chemical Abstract Service

ACGIH - American Conference of Governmental Industrial Hygienists

OSHA - Occupational Safety and Health Administration

NTP - National Toxicology program

IARC - International Agency for Research on Cancer

N/A - Not available

H - statements- Hazard statements

TLV - Threshold Limit Value

TWA - Time-weighted average

STEL - Short-Term Exposure Limit

CSA - Chemical safety assessment

Date of issue: 11/06/2015

Version no.: 1

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