According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

FORM-06-14-01 (V00)

Page 1/8

ΕN

Publication: 20/10/2022 Revision: XX/XX/XXXX

Version: 00



NATRII CITRAS

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Sodium citrate

> Natrii citras Natriumcitraat Sodium (citrate de) Natriumcitrat

N° CAS: 6132-04-3 N° EC: 612-118-5

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

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

FAC SECUNDUM ARTEM NV Company:

Oostmalsebaan 1c (unit 5)

2960 Sint-Lenaarts

Belgium

Telephone: (+32) (0)3 457 11 76 Email: info@magis-pharma.be Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation: Belgisch Antigifcentrum Centre Antipoisons Belge

(+32) (0) 70 245 245 Telephone: (Service 24/7)

www.antigifcentrum.be Web page: www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

The substance is not classified according to Regulation (EC) 1272/2008 (CLP).

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s): Not applicable. Signal word(s): Not applicable. Hazard statements: Not applicable. Precautionary statements: Not applicable. Additional applicable label Not applicable. elements:

2.3 Other hazards

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

NATRII CITRAS

FORM-06-14-01 (V00)

Page 2/8

ΕN

Publication: 20/10/2022 Revision: XX/XX/XXXX

Version: 00



None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Sodium citrate

IUPAC name: Trisodium 2-hydroxypropane-1,2,3-tricarboxylate dihydrate.

Synonyms: Trisodium citrate dihydrate

Citric acid trisodium salt dihydrate

N° CAS: 6132-04-3 N° EC: 612-118-5

Molecular Formula: C₆H₅Na₃O₇,2H₂O

Content: 99.0 per cent to 101.0 per cent (anhydrous substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: It is not specifically required. In any case, compliance with good industrial hygiene

standards is recommended.

4.2 Most important symptoms and effects, both acute and delayed

There are no known relevant acute or delayed effects from exposure to the product.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water fog.

Neighbouring fires (containers exposed to fire): Water spray or

water mist.

Unsuitable extinguishing media: Direct water jet.

5.2 Special hazards arising from the substance/mixture

Avoid breathing products derived from combustion.

5.3 Advice for firefighters

Surrounding fires: Cool containers with water to prevent decomposition of product

and development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues

in accordance with current regulations.

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

FORM-06-14-01 (V00)

Page 3/8 20/10/2022

ΕN

Publication: 20/10/2022 Revision: XX/XX/XXXX

Version: 00



NATRII CITRAS

Protection against fire: Helmet with visor, flame retardant clothing (jacket and trousers with

straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

In case of vapours or dust dispersed in the air, use respiratory protection.

For emergency responders

In case of vapours or dust dispersed in the air, use respiratory protection.

6.2 Environmental precautions

Prevent further leakage or spillage if this can be done safely. Do not allow product to enter sewage system. Discharge into the environment should be avoided.

6.3 Methods and material for containment and cleaning up

Collect and prepare disposal without creating dust. Clean and shovel. Store in appropriate closed containers for disposal.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Not available.

Personal protection: Avoid contact with eyes and skin.

Technical protective measures: Avoid formation of dust and aerosols. Adequate extraction should

be provided where dust is formed.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: In an airtight container.

Conditions for safe storage, including any

incompatibilities:

Store in a cool place. Keep container tightly closed in a dry and well-

ventilated place.

Do not store at temperatures above 30 °C.

Storage – away from: Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

FORM-06-14-01 (V00)

Page 4/8

ΕN

Publication: 20/10/2022 Revision: XX/XX/XXXX

Version: 00



NATRII CITRAS

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction.

When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations.

Provide an emergency shower with a viscoelastic tray.

Individual protection measures

No protection is required for this product. Eye/face protection: Skin protection: No protection is required for this product. Hand protection: No protection is required for this product. Respiratory protection: No protection is required for this product.

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

White or almost white, crystalline powder or white or almost white, granular Appearance:

crystals, slightly deliquescent in moist air.

Odour: Characteristic. Odour threshold: Not available.

7.5 - 9.0 (25 °C, 5 %) pH:

Melting/freezing point: > 150 °C

Initial boiling point: Not available. Boiling range: Not available. Not available. Flash point: Evaporation rate: Not available. Flammability (solid/gas): Not available. Upper/lower flammability or

explosive limits:

Not available.

Vapour pressure: Not available. Vapour density: Not available. Relative density: Not available.

Solubility: Practically insoluble in ethanol (96 per cent).

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

NATRII CITRAS

FORM-06-14-01 (V00)

Page 5/8

ΕN

Publication: 20/10/2022 Revision: XX/XX/XXXX

Version: 00



425 g/l

Partition coefficient

LogPow = -1.8 / -0.2

Freely soluble in water.

(n-octanol/water):

Solubility in water:

Auto-ignition temperature: 400 °C

Decomposition temperature: Not available.

Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Total solids (250 °C): 100.00 %

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable if used properly.

No special conditions.

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

None in particular.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:

Not available.

Skin corrosion/irritation:

Not available.

Serious eye damage/irritation:

Respiratory/skin sensitisation:

Not available.

Germ cell mutagenicity:

Not available.

Carcinogenicity:

Not available.

Reproductive toxicity:

Not available.

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

NATRII CITRAS

FORM-06-14-01 (V00)

Page 6/8

ΕN

Publication: 20/10/2022 Revision: XX/XX/XXXX

Version: 00



Summary of evaluation of the

Not available.

CMR properties:

STOT-single exposure: Not available.

STOT-repeated exposure: Not available.

Aspiration Hazard: Not available.

Other: Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:

Skin contact:

Not available.

Inhalation:

Ingestion:

Aspiration:

Not available.

Not available.

Not available.

Not available.

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

PBT/vPvB assessment is not available as chemical safety assessment is not required/not performed.

12.6 Other adverse effects

Use in accordance with good working practices, avoiding dispersal of the product into the environment. Notify the competent authorities if the product reaches watercourses, sewers, soil or vegetation.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

FORM-06-14-01 (V00)

Page 7/8

ΕN

Publication: 20/10/2022 Revision: XX/XX/XXXX

Version: 00



NATRII CITRAS

14.1 UN Number

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.2 UN proper shipping name

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.4 Packing group

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.5 Environmental hazards

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.6 Special precautions for user

It is not dangerous in transport.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable. Risk phrases: Not applicable. Not applicable. Safety phrases:

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

European Agreement concerning the International Carriage of Dangerous Goods by ADR:

CAS: Chemical Abstracts Service (division of the American Chemical Society)

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

FORM-06-14-01 (V00)

Page 8/8

ΕN

Publication: 20/10/2022 Revision: XX/XX/XXXX

Version: 00



NATRII CITRAS

EC (number): European Community (number)

IATA: International Air Transport Association
ICAO: International Civil Aviation Organization

IMDG: International Maritime Code for Dangerous Goods
 IUPAC: International Union of Pure and Applied Chemistry
 PBT: Persistent, Bioaccumulative and Toxic substance

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail

STOT: Specific Target Organ Toxicity
UN (number): United Nations (number)

vPvB: very Persistent and very Bioaccumalative

16.3 Key literature references/sources for data

European Chemicals Agency.

https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

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