

SAFETY DATA SHEET



according to Regulation (EC) No 1907/2006 (REACH) as amended

Sodium citrate dihydrate

Creation date 01st June 2021
Revision date 30th August 2024 Version 1.3

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

1.1. Product identifier Sodium citrate dihydrate
Substance / mixture substance
Chemical name Trisodium citrate dihydrate
CAS number 6132-04-3
EC (EINECS) number 200-675-3

1.2. Relevant identified uses of the substance or mixture and uses advised against
Substance's intended use
Ingredient for cosmetics. Medicinal products. Food additive. Feed additive.
Substance uses advised against

1.3. Details of the supplier of the safety data sheet

Manufacturer

Name or trade name Macco Organiques, s.r.o.
Address Zahradní 1938/46c, Bruntál 1, 792 01
Czech Republic
Identification number (CRN) 26819210
VAT Reg No CZ26819210
Phone +420 555 530 300
E-mail macco@macco.cz

Competent person responsible for the safety data sheet

Name Petr Ševčík
E-mail petr.sevcik@macco.cz

1.4. Emergency telephone number
European emergency number: 112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
Classification of the substance in accordance with Regulation (EC) No 1272/2008
The substance is not classified as dangerous according to Regulation (EC) No 1272/2008.

2.2. Label elements

Signal word

none

2.3. Other hazards

The substance does not have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Substance does not meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

SECTION 3: Composition/information on ingredients

3.1. Substances

Chemical characterization

The substance specified below.

| Identification numbers | Substance name | Content in % weight | Classification according to Regulation (EC) No 1272/2008 | Note |
|---------------------------------|--|---------------------|--|------|
| CAS: 6132-04-3 EC: 200-675-3 | substance main component Trisodium citrate dihydrate | 100 | not classified as dangerous | |

Full text of all classifications and hazard statements is given in the section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

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If inhaled

Terminate the exposure immediately; move the affected person to fresh air.

If on skin

Remove contaminated clothes.

If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person.

If swallowed

Rinse out the mouth with clean water. In the event of issues, find medical help.

4.2. Most important symptoms and effects, both acute and delayed

If inhaled

Not expected.

If on skin

Not expected.

If in eyes

Not expected.

If swallowed

Not expected.

4.3. Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Accommodate extinguishing components to the location of fire.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves. Use a self-contained breathing apparatus and full-body protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Follow the instructions in the Sections 7 and 8.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

6.3. Methods and material for containment and cleaning up

Place the product mechanically in an appropriate manner. Dispose of the collected material according to the instructions in the section 13.

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose.

7.3. Specific end use(s)

not available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Not specified.

8.2. Exposure controls

Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest. Follow the usual measures intended for health protection at work and especially for good ventilation. Provide showers and eye wash possibility.

Eye/face protection

Protective goggles.

Skin protection

Hand protection: Protective gloves resistant to the product. When handling in long-term or repeatedly, use protective gloves.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Thermal hazard

Not available.

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|--|---|
| Physical state | solid |
| Colour | white |
| Odour | without fragrance |
| Melting point/freezing point | cannot be determined - decomposition occurs |
| Boiling point or initial boiling point and boiling range | cannot be determined - decomposition occurs |
| Flammability | non-flammable |
| Lower and upper explosion limit | not applicable |
| Flash point | not applicable |
| Auto-ignition temperature | not applicable |
| Decomposition temperature | 150 °C |
| pH | 7.5-8.7 (5% solution at 20 °C) |
| Kinematic viscosity | not applicable |
| Solubility in water | 400-700g / l 20°C |
| Partition coefficient n-octanol/water (log value) | -0.2 - -1.8 |
| Vapour pressure | not applicable |
| Density and/or relative density | |
| Density | 1.86 g/cm ³ at 20 °C |
| Relative vapour density | not applicable |
| Particle characteristics | data not available |
| Form | solid: crystalline |

9.2. Other information

| | |
|----------------------|---|
| Oxidising properties | It is not oxidising. |
| Explosive properties | The product does not have explosive properties. |

SECTION 10: Stability and reactivity

10.1. Reactivity

The substance is non-flammable.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

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10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

No toxicological data is available for the substance.

Acute toxicity

Based on available data the classification criteria are not met.

| Trisodium citrate dihydrate | | | | | | | | |
|-----------------------------|------------------|----------|----------------|---------------|----------------------------------|-----|---------------------|--------|
| Route of exposure | Parameter | Method | Value | Exposure time | Species | Sex | Value determination | Source |
| Oral | LD ₅₀ | OECD 401 | 5400 mg/kg bw | | Mouse | F/M | Experimentally | ECHA |
| Dermal | LD ₅₀ | OECD 402 | >2000 mg/kg bw | | Rat (<i>Rattus norvegicus</i>) | F/M | Experimentally | ECHA |

Skin corrosion/irritation

Based on available data the classification criteria are not met.

| Trisodium citrate dihydrate | | | | | | |
|-----------------------------|----------------|----------|---------------|---------|---------------------|--------|
| Route of exposure | Result | Method | Exposure time | Species | Value determination | Source |
| Dermal | Not irritating | OECD 404 | 72 hours | Rabbit | Experimentally | ECHA |

Serious eye damage/irritation

Based on available data the classification criteria are not met.

| Trisodium citrate dihydrate | | | | | | |
|-----------------------------|----------------|----------|---------------|---------|---------------------|--------|
| Route of exposure | Result | Method | Exposure time | Species | Value determination | Source |
| Eye | Not irritating | OECD 405 | 72 hours | Rabbit | Experimentally | ECHA |

Respiratory or skin sensitisation

Based on available data the classification criteria are not met.

| Trisodium citrate dihydrate | | | | | | | |
|-----------------------------|-----------------|----------|------------------------|---|-----|---------------------|--------|
| Route of exposure | Result | Method | Exposure time | Species | Sex | Value determination | Source |
| Skin | Not sensitizing | OECD 406 | 48 hours (24 hour/day) | Guinea-pig (<i>Cavia aperea f. porcellus</i>) | M | Experimentally | ECHA |

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Germ cell mutagenicity

Based on available data the classification criteria are not met.

| Trisodium citrate dihydrate | | | | | | |
|-----------------------------|----------|---------------|-----------------------|-----------------------------------|-----|--------|
| Result | Method | Exposure time | Specific target organ | Species | Sex | Source |
| Negative | OECD 471 | | | Bacteria (Salmonella typhimurium) | | ECHA |

Carcinogenicity

Based on available data the classification criteria are not met.

| Trisodium citrate dihydrate | | | | | | |
|-----------------------------|-----------|-------|-----------|-------------------------|-----|--------|
| Route of exposure | Parameter | Value | Result | Species | Sex | Source |
| Oral | NOAEL | | No effect | Rat (Rattus norvegicus) | F/M | ECHA |

Reproductive toxicity

Based on available data the classification criteria are not met.

| Trisodium citrate dihydrate | | | | | | | |
|-----------------------------|-------------------------|------------|-----------------------|-----------|-------------------------|-----|--------|
| Effect | Parameter | Value | Exposure time | Result | Species | Sex | Source |
| Maternal toxicity | NOAEL (F ₁) | <295 mg/kg | 10 days (1 days/week) | No effect | Rat (Rattus norvegicus) | F | ECHA |

Toxicity for specific target organ - single exposure

No data available for the substance. Based on available data the classification criteria are not met.

Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

| Trisodium citrate dihydrate | | | | | | | |
|-----------------------------|-----------|------------------|---------------|-----------|-------------------------|-----|--------|
| Route of exposure | Parameter | Value | Exposure time | Result | Species | Sex | Source |
| Intraperitoneally | NOAEL | 250 mg/kg bw/day | 10 days | No effect | Rat (Rattus norvegicus) | | ECHA |

Aspiration hazard

No data available for the substance. Based on available data the classification criteria are not met.

11.2. Information on other hazards

The substance does not have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 12: Ecological information

12.1. Toxicity

Based on available data the classification criteria are not met.

Acute toxicity

| Trisodium citrate dihydrate | | | | | |
|-----------------------------|----------|---------------|-----------------------|-------------|--------|
| Parameter | Value | Exposure time | Species | Environment | Source |
| LC ₅₀ | 590 mg/l | 48 hours | Fish (Leuciscus idus) | Fresh water | ECHA |

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| Trisodium citrate dihydrate | | | | | |
|-----------------------------|-----------|---------------|-------------------------|-------------|--------|
| Parameter | Value | Exposure time | Species | Environment | Source |
| EC ₅₀ | 2055 mg/l | 24 hours | Daphnia (Daphnia magna) | Fresh water | ECHA |

12.2. Persistence and degradability

The following data are available.

Biodegradability

| Trisodium citrate dihydrate | | | | | | |
|-----------------------------|-----------|-------|---------------|-------------|----------------------|--------|
| Parameter | Method | Value | Exposure time | Environment | Result | Source |
| | OECD 301E | 100 % | 19 days | Fresh water | Easily biodegradable | ECHA |

12.3. Bioaccumulative potential

The following data are available.

| Trisodium citrate dihydrate | | | | | | | |
|-----------------------------|----------|---------------|---------|-------------|------------------|---------------------|--------|
| Parameter | Value | Exposure time | Species | Environment | Temperature [°C] | Value determination | Source |
| BCF | 3.2 l/kg | | | Fresh water | | Estimated value | ECHA |

12.4. Mobility in soil

No data available for the substance.

12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

12.6. Endocrine disrupting properties

This substance does not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in section B of Regulation (EU) No 2017/2100.

12.7. Other adverse effects

Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

Waste type code

06 03 14 solid salts and solutions other than those mentioned in 06 03 11 and 06 03 13

Packaging waste type code

06 03 00 wastes from the MFSU of salts and their solutions and metallic oxides

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SECTION 14: Transport information

- 14.1. UN number or ID number**
not subject to transport regulations
- 14.2. UN proper shipping name**
not relevant
- 14.3. Transport hazard class(es)**
not relevant
- 14.4. Packing group**
not relevant
- 14.5. Environmental hazards**
not relevant
- 14.6. Special precautions for user**
Reference in the Sections 4 to 8.
- 14.7. Maritime transport in bulk according to IMO instruments**
not relevant

SECTION 15: Regulatory information

- 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**
Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation 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 Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
- 15.2. Chemical safety assessment**
A chemical safety assessment has not been carried out (exemption from registration).

SECTION 16: Other information

Other important information about human health protection

The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

| | |
|------------------|---|
| ADR | European agreement concerning the international carriage of dangerous goods by road |
| BCF | Bioconcentration Factor |
| CAS | Chemical Abstracts Service |
| CLP | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures |
| EC | Identification code for each substance listed in EINECS |
| EC ₅₀ | Concentration of a substance when it is affected 50 % of the population |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| EmS | Emergency plan |
| EU | European Union |
| EuPCS | European Product Categorisation System |
| IATA | International Air Transport Association |
| IBC | International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals |
| ICAO | International Civil Aviation Organization |
| IMDG | International Maritime Dangerous Goods |
| IMO | International Maritime Organization |
| INCI | International Nomenclature of Cosmetic Ingredients |
| ISO | International Organization for Standardization |
| IUPAC | International Union of Pure and Applied Chemistry |

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| | |
|---------------------|---|
| LC ₅₀ | Lethal concentration of a substance in which it can be expected death of 50% of the population |
| LD ₅₀ | Lethal dose of a substance in which it can be expected death of 50% of the population |
| log K _{ow} | Octanol-water partition coefficient |
| NOAEL | No observed adverse effect level |
| OEL | Occupational Exposure Limits |
| PBT | Persistent, bioaccumulative and toxic |
| ppm | Parts per million |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RID | Agreement on the transport of dangerous goods by rail |
| UN | Four-figure identification number of the substance or article taken from the UN Model Regulations |
| UVCB | Substances of unknown or variable composition, complex reaction products or biological materials |
| VOC | Volatile organic compounds |
| vPvB | Very persistent and very bioaccumulative |

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

not available

Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended.
REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

The changes (which information has been added, deleted or modified)

The version 1.3 replaces the SDS version from Monday, 4 September 2023. Changes were made in sections 1 and 16.

Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.