

SAFETY DATA SHEET



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

Sodium citrate dihydrate

Creation date 01st June 2021
Revision date 04th September 2023 Version 1.2

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 68-04-2
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.
Full text of all classifications and hazard statements is given in the section 16.
- 2.2. Label elements**
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: 68-04-2 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.

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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.

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.

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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	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)	Pig	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	F/M	ECHA

Reproductive toxicity

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

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		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
EC ₅₀	2055 mg/l	24 hours	Daphnia (Daphnia magna)	Fresh water	ECHA

12.2. Persistence and degradability

The following data are available.

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Biodegradability

Trisodium citrate dihydrate						
Parameter	Method	Value	Exposure time	Environment	Result	Source
	OECD 301E				Easily biodegradable	ECHA

12.3. Bioaccumulative potential

The following data are available.

Trisodium citrate dihydrate						
Parameter	Value	Exposure time	Species	Environment	Temperature [°C]	Source
BCF	3200 ml/kg			Activated sludge		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

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

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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

Not available.

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
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

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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 1.2 replaces the SDS version from 14.07.2022. Change was made in the section 15.

More information

Classification procedure - calculation method.

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.
