



SAFETY DATA SHEET L+ TARTARIC ACID
According to the regulation CE N°1907/2006



Rev 17/2020

COMERCIAL QUIMICA SARASA SL
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SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1 PRODUCT IDENTIFICATION

Product name: L - (+) Tartaric Acid, 99+%
Trade name: Natural Tartaric Acid
CAS nº: 87-69-4
EINECS nº: 201-766-0
EC nº: E334
REACH Registration Num.: 01-2119537204-47-0002

1.2 MAIN PRODUCT APPLICATIONS

Acidifier, antioxidant. Flavor enhancer and stabilizing agent.

1.3 IDENTIFICATION OF THE PRODUCER

COMERCIAL QUÍMICA SARASA, S.L.

TYDSA

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tartarico@grn.es
www.tartaricacid.com

Contact Person: coquisa@tartaricacid.com;

tartarico@grn.es

1.4 EMERGENCY TELEPHONE NUMBER

National Institute of Toxicology (Madrid) + (34) 91 56 20420

SECTION 2: IDENTIFICATION OF RISKS

2.1 CLASSIFICATION OF SUBSTANCES

According to the regulation (EU) No 1272/2008:

H318: Causes serious eye damage.

P264: Wash thoroughly after handling.

P280: Wear protective glove / protective clothing / eye protection / face protection.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310: Immediately call a CENTER OF TOXICOLOGICAL INFORMATION or a doctor/physician.

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2.2. ELEMENT OF THE LABELING

Classification in accordance to EC REG. No. 1272/2008

| | | |
|---|--|---|
| PICTOGRAM  | WARNING WORD: Danger CONTAINS: Tartaric Acid L+; (E334) | H318: Causes serious eye damage. P264: Wash thoroughly after handling. P280: Wear protective glove / protective clothing / eye protection / face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a CENTER OF TOXICOLOGICAL INFORMATION or a doctor/physician. |
|---|--|---|

2.3. OTHER RISKS

It generates dusty environment.

SECTION 3: COMPOSITION, INFORMATION AND INGREDIENTS

Chemical name: L (+) Tartaric Acid /Acid 2, 3 di hydroxy-butanedioic

CAS n°: 87-69-4

IUPAC Name: Tartaric Acid

EINECS-n°: 201-766-0

EC-n°: E334

REACH n°. 01-2119537204-47-0002

Chemical formula: C₄H₆O₆ HOOCC(HOH)C(HOH)COOH

Chemical characterization: C₄H₆O₆

Molecular weight: 150, 09 g/mol

SECTION 4: FIRST AID MEASURES

4.1 DESCRIPTION FIRST AID MEASURES

Inhalation: Move the victim to a ventilated area. If the victim does not breathe the artificial respiration will be realized. If the respiration turns out to be difficult oxygen will be provided. Provide health care if appears cough or other symptoms.

Skin: Wash the area with SOAP and water, never with solvents or thinners. If irritation persists to provide medical assistance.

Eyes: Rinse immediately under running water with eyelids open, for 15 minutes. Wash eyes with plenty of water, occasionally lifting the upper and lower eyelids. Provide medical assistance.

Ingestion: If the victim is conscious and reasoning, provide 1/2 - 1 liter of milk or water. Provide health care provider if symptoms of irritation appear. Never provoke the vomiting.

In all the cases consult with a specialist if it is necessary or to call to the emergency phone.

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4.2 MAIN SYMPTOMS AND SERIOUS AND SUBSEQUENT EFFECTS

Irritating and corrosive effects, always consult the doctor in case of doubt.

4.3 INDICATIONS OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL NEEDS FOR TREATMENT

Consult the doctor in case of exposures or call the emergency telephone (see paragraph 1.4).

SECTION 5: FIRE-FIGHTING MEASURES

5.1 EXTINGUISHING WAY

It is NOT classified like flammable. In case of fire there has to be used fire extinguisher of water, of dry froth or of Dioxide of carbon, not a direct jet of water.

Temperature of Auto-ignition: 425°C (797.00°F)

Point of Combustion: 210 °C (410.00 °F)

5.2 SPECIAL RISKS ARISING TO THE SUBSTANCE OR MIXTURE

It does not require specific conditions.

5.3 ADVICES AGAINST FIRES

Watch the wind direction and avoid spillage into sewers.

Protective equipment: according to the amount of fire autonomous respiratory equipment, gloves, glasses, thermal suit, facial mask and boots.

SECTION 6: MEASURES IN CASE OF ACCIDENTAL RELEASE

6.1 PERSONAL PREVENTION, PROTECTIVE DEVICES AND PROCEDURES IN CASE OF EMERGENCY.

Avoid dust generation, do not inhale the dust. Avoid contact with the substance. Ensure to supply fresh air in enclosed areas.

6.2 ENVIRONMENTAL PRECAUTIONS

Avoid the penetration in the sewage system.

6.3 METHODS AND MATERIALS OF CONTAINMENT AND CLEANING

Gather up and place it in a container suitable for its recovery. Avoid the generation of dust. After its collection, remove the rest with water.

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6.4 REFERENCES TO OTHER SECTIONS

For instructions of treatments of residues, see section 13.

SECTION 7: STORAGE AND HANDLING

7.1 PRECAUTIONS FOR SAFE HANDLING

Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid ingestion and inhalation. Preserve it appropriately and do not apply pressure to the packing.

7.2 CONDITIONS FOR SECURITY STORAGE, INCLUDING POSSIBLE INCOMPATIBILITIES

Keep in a cool and dry place away from incompatible substances. Store in a tightly closed container, away from heat sources. Prepare storage to local legislation. Close well and avoid spills.

7.3 ESPECIFIC END USES

None.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

8.1 CONTROL OF PARAMETERS

DN (M) ELs for workers

| EXPOSURE PATTERN | ROUTE | DESCRIPTOR | DNEL / DMEL | (CORRECTED) DOSE DESCRIPTOR |
|------------------------------|------------|--------------------------------|-----------------------|--|
| Long-term - systemic effects | Dermal | DNEL (Derived No Effect Level) | 2.9 mg/kg bw/day | NOAEL: 145 mg/kg bw/day (based on AF of 50) |
| Long-term - systemic effects | Inhalation | DNEL (Derived No Effect Level) | 5,2 mg/m ³ | NOAEC: 260.0 mg/m ³ (based on AF of 50) |

DN (M) ELs for the general population

| EXPOSURE PATTERN | ROUTE | DESCRIPTOR | DNEL / DMEL | (CORRECTED) DOSE DESCRIPTOR |
|------------------------------|------------|--------------------------------|-----------------------|---|
| Long-term - systemic effects | Dermal | DNEL (Derived No Effect Level) | 1.5 mg/kg bw/day | NOAEL: 150 mg/kg bw/day (based on AF of 100) |
| Long-term - systemic effects | Inhalation | DNEL (Derived No Effect Level) | 1.3 mg/m ³ | NOAEC: 130 mg/m ³ (based on AF of 100) |
| Long-term - systemic effects | Oral | DNEL (Derived No Effect Level) | 8.1 mg/kg bw/day | NOAEL: 810 mg/kg bw/day (based on AF of 100) |

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8.2 USE CONTROL

8.2.1- Appropriate technical control

Ensure adequate ventilation, especially in limited areas.

8.2.2- Personal protective equipment

Protective clothing should be adequate according to the location and type of work. Take off contaminated clothing. It is recommended to apply a cream to the skin. Wash your hands after using this substance.

Eyes and face protection

Wear protective goggles specific for chemical products.

Hands protection

Gloves and appropriate protective clothing must be used. If there are possibilities of contact with the hands, wear gloves according to EN374.

Respiratory protection

Use protective mask in the presence of dust. Use mask P2 for solid particles.

8.2.3. - Environment exposure controls

Do not pour waste water to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION OF THE MAIN PHYSICAL AND CHEMICAL PROPERTIES

Physical state: white solid crystalline.

Colour: White.

Odour: Odourless.

Odour threshold: No information available.

PH: 2.2 (solution 0, 1 N).

Melting point: 168-170°C.

Boiling point: 179, 1 °C.

Flash point: >100°C a 102.3 kPa (mbar).

Evaporation rate: No information available.

Flammability (solids and gases): Non-flammable.

Lower flash point: No information available.

Upper flash point: No information available.

Vapour pressure: <5 Pa at 20 °C.

Vapour density: No information available.

Relative density (water=1): 1, 76 g/cm³ a 20°C

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Solubility: 1,390Kg/L s a 20°C.
Lipid solubility: No information available.
Water solubility: 1390g/l (22°).
Decomposition temperature: No information available.
Viscosity: No information available.
Explosive properties: Not explosive.
Combustibles properties: No information available.
Oxidizing properties: Not oxidizing.

9.2 ADDITIONAL INFORMATION

Content of COV (p/p): No information available.

SECTION 10: ESTABILITY AND REACTIVITY

10.1 REACTIVITY

Stable under normal conditions.

10.2 CHEMICAL STABILITY

The product is chemically stable, under normal environmental conditions and of manipulation.

10.3 POSSIBLE DANGEROUS REACTIONS

There is no possibility.

10.4 CONDITIONS TO AVOID

High temperatures.

10.5 INCOMPATIBLES MATERIAL

Keep away from oxidizing agents and materials strongly alkaline or acid, in order to avoid possible reactions of decomposition.

10.6 DECOMPOSITION OF DANGEROUS PRODUCTS

In case of fire it can produce monoxide, dioxide of carbon and smokes.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

ACUTE TOXICITY

Oral: LD50 :> 2000 mg/kg bw for rat.

Dermatological: LC50 :> 2000mg/kg bw for rat.

Value used for CSA

LD50 (oral): 2000mg/kg bw.

LD50 (dermatological): 2000mg/kg bw.

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Justification for classification or non-classification

According to Official Journal of the European Union 1272/2008 (CLP) dated December 16th 2008, tartaric acid is non-classified in the category of toxicity of sharp danger. But it is necessary to emphasize that tartaric acid is classified in category 5 of acute oral toxicity in the GHS classification system.

SKIN IRRITATION

The test of categories of danger of sharp toxicity was realized in skins annoyed and corroded in alive according to the guideline OECD 404:

Irritation/corrosion severe skin in a GLP laboratory certificate GLP. The study can be classified like 1 according to the code Klimisch: without exact restrictions. The results show that toxic effects have not been found. Another 2 studies in Vitro corroborates this result. Therefore the irritating effects of the tartaric acid conclude like not irritant.

Evaluation used for CSA: Irritation/corrosion in the skin: Not irritant.

EYE IRRITATION

An in vitro test of the registered substance was realized on eye irritation complying with OECD Guideline 437:

Bovine Corneal Opacity and Permeability Test Method for identifying ocular corrosives and severe irritants. This study is considered as a key of the study as it can be ranked according to the Klimisch code as 1: reliable without restrictions. And the test result showed that tartaric acid is highly irritating.

Evaluation used for CSA: Eye Irritation: highly irritating.

SKYN SENSIBILITY

The following information is taken into consideration for any danger / risk: Sensibility in the skin (OECD 429): not sensitization.

Evaluation used for CSA: Not sensitization.

RESPIRATORY SENSITIZATION

Evaluation used for CSA: Not sensitization.

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TOXICITY OF REPETED DOSIS

NOAEL of toxicity of dose repeated in tartaric acid is derived across the key of the reading of the study 004. In this study, Monosodium L (+)-tartrate, fed to rats for 2 years at levels of 25600, 42240, 60160 and 76800 ppm and have not been found adverse effects in high concentrations of L (+)-tartrate.

Therefore it is reasonable, to choose 76800 ppm of tartrate, that is equivalent to 2460 mg/kg bw/day, like NOAEL of the tartaric Acid. Also, in the key study, the material used for the test was Monosodium L (+)-tartrate and a sodic salt of the tartaric acid. This can serve like a reading across study, because the basic chemical structure is the same in the two chemical examples.

The following information is taken into consideration for any danger / evaluation of risk:

Tests of adverse effects were not found in the dose of 3.1g/kg bw/day and 4.1 g/kg bw/day L (+) - tartrate, either in feminine or masculine rats, corresponding to 2.46g/kg bw/day and 3.2 g/kg bw/day L (+) - tartaric acid for rats females and masculine respectively.

Evaluation used by CSA (route: oral)

NOAEL: 2460 mg/kg bw/day (rat; chronicle).

Justification for classification or non-classification

The DNEL of repeated oral dose toxicity of tartaric acid is 2460 mg/kg bw/day, no specific organ toxicity was found here, so non-classification will be justified.

MUTAGENICITY

The FDA report, mutagenic evaluation of compound FDA 71-55, comprises several studies investigating genotoxicity of this substance in vitro and in alive. In the in vitro studies, 4 host-mediated assays including two germs (*S. typhimurium*) and two germs (*Saccharomyces cerevisiae*) tests, and a mammalian chromosome aberration test (Human embryonic lung cultures) were conducted at different concentration levels. In the a live studies, two dominant lethal tests and two mammalian bone marrow chromosome aberration tests were carried out in different series of concentrations in rats. No genetic toxicity was found in those tests either in all investigated concentrations. Therefore we can conclude that the L (+) - tartaric acid is not poisonous according to the tartaric acid that we find in the experiments in Vitro and in alive.

Value used for CSA: Genetic toxicity: negative.

CARCINOGENICITY

No data available. Combined chronic Toxicity/Carcinogenicity study equivalent or similar to OECD Guideline 453 is available under repeated dose toxicity."

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REPRODUCTIVE TOXICITY

A report by FDA, Teratology evaluation of FDA 71-55, Teratology studies are summarized of the tartaric acid in different species: mice, rats, hamster and rabbits, using toxicological test in prenatal development. In this study we find that the administration in high doses, 274 mg/kg bw in mice, 181 mg/kg bw in rats, 225 mg/kg bw in hamsters and 215 mg/kg bw in rabbits, no generated teratology effects in test animals.

So these dose levels are set as NOAEL in each individual test. In order to ensure safety, we also consider that the toxicokinetics of the tartaric acid in rats is well-studied, NOAELs in rats is selected as the descriptor for the calculation of the initial dose.

The following information is taken in the area of danger/risk evolution: the FDA report evaluation teratology for FDA 71-55, it is provided with 4 keys of study carried out in different ways of investigating the toxic development / teratology.

Assessment used by CSA (route: oral) NOAEL: 181 mg/kg bw/day

DANGER IN CASE OF INHALATION

There is no classification for inhalation toxicity

SECTION 12: ECOLOGICAL INFORMATION

12.1 TOXICITY.

ACUTE AQUATIC TOXICITY

The fish, daphnia, and algae acute aquatic toxicity levels are greater than 1 mg/L (96h LC50 (fish) > 100 mg/L, 48h EC50 (daphnia) = 93.3mg/L, and 72h ErC50 (algae) =51.4 mg/L). As a result, the substance does not meet the criteria for acute classification according to Regulation (EC) No. 1272/2008, Annex I section 4.1.

CHRONIC AQUATIC TOXICITY

The fish, daphnia, and algae acute aquatic toxicity levels are greater than 10 mg/l and lower than 100 mg/L (96h LC50 (fish) > 100 mg/L, 48h EC50 (daphnia) = 93.3mg/L, and 72h ErC50 (algae) =51.4 mg/L). As well, the substance is very soluble, ready biodegradable and has a Log Kow of -1.91. As a result, the substance does not meet the criteria for chronic classification according to Regulation (EC) No. 1272/2008, Annex I section 4.1.

12.2 PERSISTENCE ASSESSMENT

In accordance with Annex XIII to Regulation 1907/2006/EC and in agreement with the orientation of the information required and the chapter of evolution of chemical risks R.11 PBT evolution, a substance that does not fulfill the criterion of "persistent (P)" and "very persistent (vP)" it is biodegradable. As the substance is shows that is easily biodegradable with a biodegradation of more than 80% is not considered to be persistent or very persistent.

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12.3 BIOACCUMULATION ASSESS

According to Annex XIII of regulation 1907/2006/EC and according to the Guidance on information requirements and chemical safety assessment Chapter R.11 PBT assessment, a substance does not fulfil the criterion “bioaccumulative (B)” or “very bioaccumulative (vB)” if the BCF is below 2000 or the log Kow is below 4.5.

There is no experimental data on BCF. However, the log Kow is negative and below the criterion for bioaccumulation (log Kow 4.5). Therefore, it can be concluded that the substance is neither bioaccumulative nor very bioaccumulative.

12.4 TOXICITY ASSESSMENT

According to Annex XIII of regulation 1907/2006/EC and according to the Guidance on information requirements and chemical safety assessment Chapter R.11 PBT assessment, a substance does not fulfil the criterion if there is no evidence of chronic toxicity and no classification as carcinogenic (Cat. 1, 2), mutagenic (Cat. 1, 2) or toxic for reproduction (Cat 1, 2, 3) considering human health. As the substance is not toxic and not classified for human health, these criteria are not fulfilled. Furthermore, the substance is not toxic for aquatic organisms.

12.5 SUMMARY AND FINAL CONCLUSIONS ON PBT OR VPVB PROPERTIES

The substance does not fulfil the criteria for PBT or vPvB properties.

12.6 EMISSION CHARACTERISTICS

As the substance does not fulfil the criteria for PBT or vPvB, no emission assessment is required.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 METHODS OF TREATMENT OF RESIDUES

In general, the elimination of chemical residues is regulated in every country with its legislation and current specific regulations. Therefore, it is recommended to contact with the corresponding Authorities or specializing companies authorized to provide indications on the way of organizing the elimination.

The packing material must arrange agreement to itself to the national regulations. The material of contaminated packing must be manipulated by the same precautions that if we use dangerous substances. The material of not contaminated packing must be treated or recycled like a normal residue, unless the opposite is indicated.

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SECTION 14: TRANSPORT INFORMATION

UN number: NA

Shipping name: NA

Classification: Not classified ADR/RUD/AND/IMDG/IATA/ICAO

Packing group: NA

Environmental risk: NA

Special precautions for users: NA

ADR TRANSPORT /RID ROAD/RAILWAY TRANSPORT

Not classified as dangerous goods for transport.

IMDG SEA TRANSPORT

Not classified as dangerous goods for transport.

ICAO AND IATA AIR TRANSPORT

Not classified as dangerous goods for transport.

SECTION 15: REGULATION OF USE

15.1 STANDARDS LAWS IN THE FIELD OF HEALTH, SAFETY AND ENVIRONMENT SPECIFIC TO THE SUBSTANCE.

Authorization accordance to REACH Regulations:

It is not on the list of substances of very high concern (SVHC) applicable for the authorization.

Restrictions in accordance to the regulations of REACH:

It is not subject to restrictions in accordance of Title VII (Annex XVII, Appendix 2, paragraph 28). It is not affected by the Regulation (EC) No1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer. Consult annex I to Council Directive 96/82/EC on the control of risks and Regulation (EC) No 689/2008 of the European Parliament of 17 June 2008.

15.2. EVALUATION OF CHEMICAL DANGERS

It has carried out an assessment of chemical safety.

SECTION 16: ADDITIONAL INFORMATION

List of the relevant H danger indications

H318: Causes serious eye damage.

List of the relevant R phrases

R41 - Risk of serious damage to eyes.

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EXPOSURE ASSESSMENT

Overview of Exposure Scenarios for Tartaric Acid, Exposure Scenario

- 1 Manufacture of Substance – industrial.
- 2 Formulation & (Re) packing of Substances and Mixtures.
- 3 Uses as intermediate.
- 4 Uses in Construction applications – Professional.
- 5 Uses in Construction applications – Consumer.
- 6 Uses in Ceramics applications – Professional.
- 7 Uses in Ceramics applications – Consumer.

| USOS IDENTIFICADOS | | | | | | | | | | |
|--------------------|-------------|-------------|--------------|-----------|---------------------|-------------------|------------------------------|----------------------------|--------------------|---|
| Nº | Manufacture | Formulation | Intermediate | Final Use | Use by the consumer | Sector of use(SU) | Category of preparation (PC) | Category of process (PROC) | Item category (AC) | Category of environmental release (ERC) |
| 1 | X | | | | | 3, 8, 9 | 35, 39 | 1, 2, 3, 4,8a, 8b, 9 | 4 | 1 |
| 2 | | X | | | | 10, 3 | 35, 39 | 5,8a, 8b, 9 | 4 | 2 |
| 3 | | | X | | | 3, 8, 9 | 35, 39 | 1, 2, 3, 4,8a, 8b, 9 | 4 | 6a, 6b |
| 4 | | | | X | | 22 | NA | 8a, 8b, 9 | NA | 8c, 8f |
| 5 | | | | | X | 21 | NA | NA | 4 | 10a, 11a |
| 6 | | | | X | | 22 | NA | 8a, 8b, 9 | NA | 8c, 8f |
| 7 | | | | | X | 21 | NA | NA | 4 | 10a, 11a |

Instructions on training

Properly train those workers potentially exposed to this substance on the basis of the contents of this safety data sheet.

Main bibliographical references and data sources

Expediente de registro del Acido Tartárico.

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Disclaimer. This information has been obtained in chemical safety informed believe true. The conditions of handling, use or disposal are beyond our control and responsibility. This SDS is only for our product, if it is a component information may not apply. The company shall not be liable for any damage to persons or objects deriving from the improper use of the information disclosed in this document. Reason to change the data sheet: General update according to EC Regulation No. 1907/2006.



SAFETY DATA SHEET L+ TARTARIC ACID
According to the regulation CE Nº1907/2006



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Key of abbreviations and acronyms

DNEL = Derived No Effect Level.

DREL = Derived Minimum Effect Level.

EC50 = Median Effective Concentration.

IC50 = Median Lethal Concentration.

LD50 = Median Lethal Dose.

PNEC= Predicted No-Effect Concentration.

PBT = Persistent, Bioaccumulative and Toxic substance.

TLV®/TWA = Threshold limit value – time-weighted average.

VPvB = Very Persistent and Very Bioaccumulative.

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