Revision on 01/12/2010

SAFETY DATA SHEET

in compliance with EC Regulation No. 1907/2006

1 IDENTIFICATION OF SUBSTANCE AND COMPANY

1.1 *PRODUCT IDENTIFIER*

Name of the substance: L (+) Tartaric Acid (99+%)
Trade name: Natural Tartaric Acid
Registration Nr. 01-2119537204-47-0005

1.2 IDENTIFIED RELEVANT USES OF THE SUBSTANCE

Acidifier, antioxidant, flavour enhancer and stabilising agent.

1.3. DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company: Distillerie Mazzari SpA - Via Giardino, 6 48020 S.Agata sul Santerno (RA) – ITALY
Tel. +39 0545 45014 - www.mazzarispa.com - distillerie@mazzarispa.com
Person responsible for the sheet drafting: ivan@mazzarispa.com

1.4. EMERGENCY TELEPHONE NUMBER

Centro Antiveleni Azienda Ospedaliera Niguarda - Piazza dell'Ospedale Maggiore, 3 - 20162 Milan - ITALY
Tel: 02-66101029

2 HAZARDS IDENTIFICATION

2.1. CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification pursuant to EC REG. No. 1272/2008
GHS05: corrosion
H318: Causes serious eye damage
P280: Wear protective gloves/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.

Classification pursuant to REG. 67/54/EC, 1999/45/EC
Xi – IRRITANT
R41 - Risk of serious damage to eyes
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
For the complete text about hazard statements and R phrases, refer to section 16.

2.2. LABEL ELEMENTS

Classification pursuant to EC REG. No. 1272/2008
Hazard pictograms

CORROSION

Signal Word:
Danger

Hazard statements:
Causes serious eye damage

Precautionary statements:
Wear protective gloves/protective clothing/eye protection/face protection.

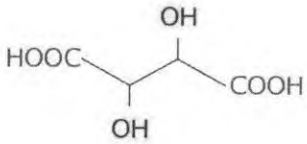
Reviewed on 3/15/2012 by NP

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

2.3. OTHER HAZARDS
No information available.

3 COMPOSITION / INFORMATION ON INGREDIENTS

CAS Number:	87-69-4 (99+%)
IUPAC Name:	Tartaric Acid
CAS Name:	Butanedioic acid, 2,3-dihydroxy- [R-(R,R)]-
EC Number:	201-766-0
Molecular weight:	150.09 g/mol
Formula:	$C_4H_6O_6$
Chemical formula:	HOOCCH(OH)CH(OH)COOH



4 FIRST AID MEASURES

4.1. FIRST AID MEASURES DESCRIPTION

Inhalation:	Remove victim from exposure and to open air. Seek medical advice, if necessary.
Skin contact:	Wash off with soap and plenty of water. Take off contaminated garments. If skin irritation persists, consult a specialist.
Eye contact:	Rinse immediately with running water with eyelids held open, for at least 10 minutes. Call an eye specialist, if necessary.
Ingestion:	Make the victim drink plenty of water. Call a doctor, if necessary.

4.2. MAIN SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED
Irritating effects.

4.3. INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED
Call a doctor in case of exposure.

5 FIRE FIGHTING MEASURES

5.1. EXTINGUISHING MEDIA
Suitable extinguishing media: Water, CO_2, Foam, Powder.
Extinguishing media not to be used: No limits.

5.2. SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE
In case of fire, gas and hazardous vapours may be formed.

5.3. ADVICE FOR FIRE-FIGHTERS
Protective equipment: Do not stay in the hazardous area without a self-contained breathing apparatus.

6 ACCIDENTAL RELEASE MEASURES

6.1. PERSONAL PRECAUTIONS, PROTECTION DEVICES AND PROCEDURES IN CASE OF EMERGENCY
Avoid generation of dust, do not inhale dust. Avoid contact with the substance. Ensure the supply of fresh air in closed rooms.

6.2. ENVIRONMENTAL PRECAUTIONS
Avoid penetration into the sewerage system.

6.3. METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP
Collect and place them in a container suitable for recovery. Avoid generation of dust. After collection, flush away traces with water.

6.4. REFERENCES TO OTHER SECTIONS
For instructions on waste treatment, see section 13.

7 HANDLING AND STORAGE

7.1. PRECAUTIONS FOR SAFE HANDLING
Use with adequate ventilation system. Minimise dust generation and accumulation. Avoid contact with eyes, skin and clothing. Keep the container tightly closed. Avoid ingestion and inhalation.

7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING POSSIBLE INCOMPATIBILITIES
Store in a tightly closed container. Store in a fresh and dry area.

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7.3. SPECIFIC END USES
See paragraph 1.2

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. CONTROL 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/m³	NOAEC: 260.0 mg/m³ (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/m³	NOAEC: 130 mg/m³ (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)

8.2. EXPOSURE CONTROLS

8.2.1. *Suitable technical controls*
Ensure adequate ventilation, especially in confined areas.

8.2.2. *Personal protection measures*
Protective clothing should be selected specifically for the working place and type of work. Take off any contaminated garments. It is advisable to apply protective cream for the skin. Wash hands after handling this substance.

Eyes/face protections
Wear protective goggles against chemicals.

Hands protection
If hands contact is likely to occur, wear suitable gloves tested according to EN374. Suitable gloves and protection garments should be worn.

Respiratory protection
Wear a protective mask in the presence of dust. Use the P2 Filter for solid particles.

8.2.3. Environment exposure controls
Do not pour waste waters directly into the environment.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1. INFORMATION ON 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:	169 °C at 1013 hPa (mbar)
Boiling point:	179.1 °C at 1013 hPa (mbar)
Flash point:	> 100 °C at 102.3 kPa (mbar)
Evaporation rate:	*No information available*
Flammability (solids, 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/cm^3 at 20°C

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Solubility:	1,390 g/L at 20 °C.
Partition coefficient:	n-Octanol/water: Log Kow (Pow): - 1.91 at 20 °C
Autoflammability:	375 °C at 1,013 hPa
Decomposition temperature:	*No information available.*
Viscosity:	*No information available.*
Explosive properties:	*Not explosive.*
Oxidising properties:	*Not oxidising.*

10 STABILITY AND REACTIVITY

10.1. REACTIVITY
Stable under normal conditions.

10.2. CHEMICAL STABILITY
The product is chemically stable under standard environmental conditions.

10.3. POSSIBLE HAZARDOUS REACTIONS
Fluorine, metals, silver

10.4. CONDITIONS TO AVOID
Strong heating.

10.5. INCOMPATIBLE MATERIALS
No information available.

10.6. HAZARDOUS DECOMPOSITION PRODUCTS
No information available.

11 TOXICOLOGICAL INFORMATION

11.1. INFORMATION ON TOXICOLOGICAL EFFECTS

ACUTE TOXICITY

Oral: LD50: > 2000 mg/kg bw for rat
Dermal: LD50: > 2000 mg/kg bw for rat
Value used for CSA:
LD50 (oral): 2000 mg/kg bw
LD50 (dermal): 2000 mg/kg bw
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 acute toxicity hazard categories. 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:

A test of the registered substance was performed on skin irritation/corrosion *in vivo* according to OECD Guideline 404: acute dermal irritation/corrosion in a certified GLP lab. The study can be ranked according to the klimisch code as 1: reliable without restrictions. The results showed that no toxic effect was found. And other two *in vitro* studies also support this result. So the irritating effect of tartaric acid can be concluded as no irritating.
Value used for CSA: Skin irritation / corrosion: not irritating.

EYE IRRITATION:

An in vitro test of the registered substance was performed 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 regarded as key 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.
Value used for CSA: Eye irritation: highly irritating

SKIN SENSITISATION

The following information is taken into account for any hazard / risk assessment:
Skin sensitisation (OECD 429): not sensitising.
Value used for CSA: Not sensitising.

RESPIRATORY SENSITISATION

Values used for CSA: No data available.

REPEATED DOSE TOXICITY

NOAEL of repeated oral dose toxicity of tartaric acid is derived from the key study 004 through read across. In this study, Monosodium L(+) -tartrate was fed to rats in their diet for a total of two years at levels of 25600,

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42240, 60160 and 76800 ppm and no adverse effect was observed in the highest concentration of L(+) -tartrate. So it is reasonable to choose 76800 ppm tartrate, which is equal to 2460 mg/kg bw/day, as NOAEL of tartaric acid. Furthermore, in the key study, the test material used was Monosodium L (+) -tartrate, a sodium salt of tartaric acid. It can be served as a read across study, because the basic chemical structures are the same in such two chemicals.
The following information is taken into account for any hazard / risk assessment:
No evidence of an adverse effect was seen in the dose of 3.1 g/kg bw/day and 4.1 g/kg bw/day L(+) -tartrate for male and female rats respectively, corresponding to 2.46 g/kg bw/day and 3.2 g/kg bw/day L(+) -tartaric acid for male and female rats respectively.
Value used for CSA (route: oral):
NOAEL: 2460 mg/kg bw/day (chronic; rat)
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 vivo. In the in vitro studies, 4 host-mediated assays including two bacteria (S. typhimurium) and two yeast (Saccharomyces cerevisiae) tests, and a mammalian chromosome aberration test (Human embryonic lung cultures) were conducted at different concentration levels. In the in vivo 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 in all investigated concentrations. So it can be concluded that L(+) -tartaric acid is non-mutagenic.
The following information is taken into account for any hazard / risk assessment: no genetic toxicity of tartaric acid was found through in vitro and in vivo experiments.
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.

REPRODUCTIVE TOXICITY

The FDA report, teratologic evaluation of FDA 71-55, summarised studies of the teratogenicity of tartaric acid in different species: mouse, rat, hamster and rabbit, using prenatal developmental toxicity test. It is found that administrations of the highest dosage, 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, did not generate any teratogenic effects on tested animals. So these dose levels could be set as NOAELs in each individual test. In order to guarantee safety, also considering that the toxicokinetics of tartaric acid in rat is well studied, NOAEL of rat is chosen as the dose descriptor starting point for further calculation.
The following information is taken into account for any hazard/risk assessment: The FDA report, teratologic evaluation of FDA 71-55, includes 4 key studies carried out in different species investigating the developmental toxicity/teratogenicity. No teratogenic effect was found in these studies.
Value used for CSA (route: oral): NOAEL: 181 mg/kg bw/day

HAZARD IN CASE OF INHALATION

No inhalation toxicity classification.

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

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

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"persistent (P)" and "very persistent (vP)" if it is readily biodegradable. As the substance is shown to be readily biodegradable with a biodegradation of above 80% it is not regarded as persistent or very persistent.

12.3 BIOACCUMULATION 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 "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.

13 DISPOSAL CONSIDERATIONS

13.1. METHODS FOR WASTE TREATMENT

In general, the disposal of chemical residues is regulated in each European country by specific laws and regulations.
In Italy, the disposal must occur according to the laws in force and in compliance with local laws. Therefore, it is recommended to contact the Authorities in charge or specialised Companies authorised to provide indications on how to arrange the disposal.
Packing material must be disposed of in accordance with national regulations. Contaminated packing material must be handled with the same caution used for dangerous substances. Non-contaminated packing material can be treated or recycled as normal residues, unless otherwise indicated.

14 TRANSPORT INFORMATION

ADR/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.

15 REGULATORY INFORMATION

15.1. STANDARDS AND LAWS ON HEALTH, SAFETY AND ENVIRONMENT SPECIFIC FOR THE SUBSTANCE

Authorisation pursuant to REACH Regulations:
It is not on the list of substances of very high concern (SVHC) applicable for the authorisation.

Restrictions on use pursuant to REACH Regulations:
It is not subject to restrictions pursuant to Title VII (Annex XVII, Appendix 2, paragraph 28)

15.2 CHEMICAL SAFETY ASSESSMENT

An assessment of the chemical safety has been carried out

16 OTHER INFORMATION

List of the relevant H hazard indications:
H318: Causes serious eye damage

List of the relevant R phrases:
R41 - Risk of serious damage to eyes

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