



Specification

Product Name: Tartaric Acid

Product Code: SPEC0056

Description:

Our Tartaric Acid is a premium quality, white, odourless crystalline powder with a slight tart taste. Tartaric Acid is very versatile and can be used as an emulsifier, bulking agent, acidifying agent and dough conditioner. Use in a variety of ways such as improving the quality and increasing the shelf life of cheese and tofu, adding to pate de fruit or jams to activate Pectin, adding to baked goods as a leavening agent to improve the quality and colour of flour. It also interacts with gelling agents to strengthen food structure and is commonly used in winemaking to maintain colour, stability and taste.

Specifications:

Commercial name: L-(+)-Tartaric Acid

IUPAC name: (2R,3R)-2,3-Dihydroxybutanedioic acid

CAS code: 87-69-4

EINECS code: 201-766-0

Formula: C₄H₆O₆

Molecular weight: 150.09

	Specifications
Description	White or almost white crystalline powder
Identification	Meets identification tests
Assay	99,7 – 100,5
Appearance of solution	Clear and less coloured than reference solution
Specific optical rotation	12,0 – 12,8
Loss on drying	<0,2%
Sulphates	<150 ppm
Sulphates ash	<0,05%
Oxalates	<100 ppm
Mercury	<1 ppm
Lead	<2 ppm
Heavy metals (Pb)	<10 ppm
Chlorides	<100 ppm
Calcium	<200 ppm
Arsenic	<1 ppm
Iron	<5 ppm

The above results confirm that the product meets the requirements of the following pharmacopeia: Ph.Eu.VII - F.U.XII - U.S.P. XXXVI-NF31 - F.C.C. VIII - J.P. XVI - REG.(UE) N.231/2012.

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**Ingredients:**

Tartaric Acid (E334).

Dietary Information:

Suitable for Vegans & Vegetarians, Non-GMO, Gluten Free.

Nutritional Information:

Based on typical content/100g: Energy: 1300kj/300kCal, Fat: 0g, Carbohydrate: 0g, Protein: 0g, Salt: <0.001g.

Storage:

Store in dry, cool conditions out of direct sunlight.

Packaging:

Size	EAN
100g	5060341110351
200g	5060341110368
500g	5060341110375
5kg	5056191005084
10kg	5056191005091

Shelf Life:

48 months from production date.

Allergen Declaration

Allergen	Contains (Y/N)
Cereals containing Gluten	N
Crustaceans	N
Eggs	N
Fish	N
Peanuts	N
Soybeans	N
Milk	N
Nuts	N
Celery	N
Mustard	N
Sesame Seeds	N
Sulphur Dioxide and Sulphites (at concentration of more than 10mg/kg or 10mg/L in terms of Sulphur Dioxide)	N
Lupin	N
Molluscs	N



Material Safety Data Sheet

1: Substance/Preparation and Company Identification:

1.1 – Product Identifier

EC name: L(+)-Tartaric Acid

EC Number: 201-766-0

CAS Number: 87-69-4

Other means of identification: Natural Tartaric Acid

1.2 – Relevant identified uses of the substance or mixture and uses advised against

Acidifier, antioxidant, flavour enhancer and stabilising agent.

Food industry (production of tinned food, jam, jelly, confectionery and biscuits in general, soft drinks and table waters; acidifier in wine-making field). Pharmaceutical and Cosmetic Industry (preparation of medicines, effervescent tablets and soluble drugs; excipient, acidifier in syrups and antibiotics and food additive; production of natural beauty cream for face and body) and Industrial and Technical (retarding agent in the preparation of gypsum, used in the formulation of waterproof cements and heat-insulator; it is also used in textiles, tannings, ceramics, galvanoplastics, cleaning agents, used as laboratory reagent, mining and offshore industries).

Uses advised against:

There are no uses advised against.

1.3 – Suppliers Details

Special Ingredients Ltd, 4 Foxwood View, Chesterfield, S41 9RN. Tel: 0044 (0)1246 906247.

E-mail address: <https://specialingredients.co.uk/pages/contact>.

Emergency Telephone Contact: 07387 330318.

2: Hazard Identification:

Physicochemical hazards:

The substance is solid and does not present any physicochemical hazards arising from its intrinsic properties.

Hazards to human health:

The substance causes serious eye damage.

Environmental hazards:

The substance is not dangerous for the environment.

PBT/vPvB evaluation:

The substance does not meet the PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative).

2.1 – Classification of the substance or mixture

Classification according to EC Regulation 1272/2008 (CLP):

Eye Dam.: 1 H318

Serious eye damage, hazard category 1; Causes serious eye damage.

2.2 – Label elements

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Labelling in accordance with Regulation (EC) No 1272/2008:

GHS pictogram:

GHS05: Corrosion



Signal word: Danger

Hazard statements:

H318: Causes serious eye damage.

Precautionary statements:

P264: Wash hands thoroughly after handling

P280: Wear protective gloves/ protective clothing/eye protection/face protection. P310: Immediately call a POISON CENTER/doctor.

P305 + P351 + P338: 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

The substance is solid: consider – and when required control – hazards arising from dust formation during use. No further dangers have been identified.

Tartaric acid is not considered to be PBT / vPvB (persistent, bioaccumulative and toxic / very persistent and very bioaccumulative).

3: Composition and Information on Ingredients:**3.1 – Substances**

Tartaric Acid is a mono-constituent substance, of organic origin, identified as stated below: EC Name: L(+)-tartaric acid

EC Number: 201-766-0

CAS Number: 87-69-4

Constituent	Typical concentration	Concentration range
Tartaric acid	99,9%	>99,7%

3.2 – Mixtures

Not applicable.

4: First Aid Measures:**4.1 – Description of first aid measures**

General first aid principles – Important information:

In the event of doubts, or if symptoms occur, contact a physician and show this Safety Data Sheet. In the presence of more serious symptoms, call the national emergency service to obtain immediate first aid. Call a poison control centre to receive detailed information for the clinical management of the poisoning case. Never give anything by mouth to a victim who is unconscious.

General first aid principles – Inhalation:

Remove the injured person from the source of exposure. In case of respiratory symptoms (cough,



dyspnea, respiratory difficulty, asthma), keep the injured person in a semi-seated position and administer oxygen if necessary. If the subject stops breathing, administer artificial respiration.

General first aid principles – Contact with the skin:

Wash the affected area with plenty of water (and soap if possible) for 15 minutes. In case of irritation or pain, get medical advice.

General first aid principles – Contact with the eyes:

Remove contact lenses, if this can easily be done. Wash with plenty of water for at least 15 minutes, opening the eyelids fully. In any case, especially in the presence of symptoms of irritation (redness, lacrimation, pain, foreign body sensation), immediately consult an ophthalmologist.

General first aid principles – Ingestion:

Do not induce vomiting. Do not administer anything by mouth without prior indications given by a poison control centre. Wash the oral cavity with running water and consult a doctor.

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

Acute effects:

At the date of drawing up of this Safety Data Sheet, no cases of acute human poisoning from exposure to this substance are known. On the basis of the experimental data observed, irritant or corrosives effects may occur when skin and mucous membranes come into contact with the substance (skin, eyes).

Delayed effects:

At the date of drawing up of this safety sheet, no effects in human beings arising from chronic exposure to this substance are known.

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

Need for medical attention:

In case the victim shows serious symptoms call the national emergency service immediately to obtain first aid. In any case it is recommended to contact a poison control centre to get expert toxicological advice right from the very first steps of first aid. If symptoms persist – even minor ones – get medical attention.

Special treatments and antidotes that must be available at the workplace:

Water for skin and eye wash. Oxygen.

Personal protective equipment for first aid responders:

Wear protective clothing to avoid contamination of responders during first aid operations.

Removal and handling of contaminated clothing:

In the event of important contamination, remove the clothing and put it into a closed container away from the work area.

5: Firefighting Measures:

General information:

Remove the non-specialists and stay upwind. Do not enter in closed spaces without an appropriate protection.

5.1 – Extinguishing media

Suitable extinguishing media:

The extinction equipment used should be of the conventional kind. The suggested devices are

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nebulized water, foam, powder. In selecting the extinguishing media, take into account the other materials involved in the fire.

Extinguishing media which shall not be used for safety reasons:

None in particular.

5.2 – Special hazards arising from the substance or mixture

In case of fire, irritant or toxic fumes can develop from the substance or the other materials. Compounds like carbon monoxide (CO) and carbon dioxide (CO₂) can develop because of heating at temperatures exceeding the decomposition temperature.

5.3 – Advice for firefighters

In case of fire, when this substance is involved, a special protective equipment is not needed. Wear fireproof clothing, like firemen's one. In case of fire in enclosed and inadequately ventilated spaces, wear a complete fireproof protective equipment and a self-respirator.

6: Accidental Release Measures:

6.1 – Personal precautions, protective equipment and emergency procedures

Remove the employees that are not involved from the spillage area and call the emergency teams. Stop or contain the spillage at source, if security conditions permit. Avoid direct contact with the released material. Stay upwind. In case of small spillages, the working clothes are generally adequate. In case of big spillages, a protective equipment made of appropriate material may be necessary. Protective devices may also be necessary, as stated in Section 8.

6.2 – Environmental precautions

Collect the spilled substance in appropriate containers. In order to prevent the formation of dusts, humidify the substance before doing it if necessary. Collect the residue cautiously and apply it for correct disposal. Avoid the product discharging into the sewerage system, rivers or other water bodies. In case of contamination of rivers, lakes or sewers, inform the competent authorities.

6.3 – Methods and material for containment and cleaning up

Land spreading:

Big overflows of substance can be mechanically removed and the residues can be washed with water. Operate in accordance with the good working practices and refer to specialized services, if necessary.

Spillages in water:

At the time of drafting this Safety Data Sheet, indications concerning specific procedures to adopt, to contain and clean up after the spillage in water of the substance, are not known. Operate in accordance with the good working practices and refer to specialized services, if necessary.

6.4 Reference to other sections

Any other information is given in sections 8 and 13.

7: Handling And Storage:

7.1 – Precautions for safe handling

General recommendations:

While handling the substance, you have to avoid the formation of dusts and the release of the product in the air. Specialized staff have to be in charge of loading, unloading and handling. The substance



has to be handled in an adequately ventilated space. Clean the equipment and the working area regularly. Avoid the contact with the skin and the eyes. In case of possible contact with the skin and the eyes, protective gloves and glasses have to be worn.

Recommendations on personal care:

Do not breath dust. Avoid the contact with the skin and the eyes. Do not eat, drink or smoke in the working area. Wash hands thoroughly after handling. Do not reuse contaminated clothes and wash them before wearing again.

7.2 – Conditions for safe storage, including any incompatibilities

The structure of the storage area, the features of the tanks, the systems and the operative procedures have to be in line with the relevant legislation on a European, national and local level. The storage plants have to be equipped with appropriate systems to prevent the soil and water contamination, in case of leakages or spillages. Keep in closed containers, far from incompatible products (oxidizing substances, bases, reducing agents and silver), avoiding high temperatures and freezing.

7.3 – Specific end use(s)

There are no specific indication concerning handling and storage, with respect to the end uses of the substance.

8: Exposure Controls:

8.1 – Control parameters

No specific occupational exposure limit values have been set for this substance on a national or European level. Other occupational exposure limit values, which have been determined, are listed here below:

Countries	Limit values (8 hours)		Limit values (short term)	
	ppm	mg/m ³	Ppm	mg/m ³
Germany (AGS)	-	2 (1)	-	4 (1) (2)
Germany (DFG)	-	2 (1)	-	4 (1) (2)
Switzerland	-	2 (1)	-	4 (1) (2)

(1): inhalable fraction; (2): 15 minutes, average value

DNEL (Derived No-Effect Level):

Tartaric acid exerts its irritant/corrosive effect without evidence of a dose-response relationship. Hence, available data do not allow to establish a threshold above which the substance exerts its irritant/corrosive effect. Consequently, no DNEL value has been set. For a proper management of the risks associated to the occupational use of this substance, a qualitative approach appears to be the most appropriate, as described in the Annex to the Safety Data Sheet.

PNEC (Predicted No-Effect Concentration):

No adverse effect has been observed in studies at the highest recommended concentrations/doses tested. For this reason, the definition of PNEC values is not required for environmental compartments.

8.2 – Exposure controls

Adequate technical controls:

Minimize exposure to dusts. When the substance is not produced, used or transformed in a closed and controlled system, risk reduction measures can be necessary (for example, Local Exhaust Ventilation System for dust capturing, protective gloves, protective glasses).

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Measures and devices for individual protection:

Eyes protection: In case of possible contact with the eyes, wear a visor or protective gloves in accordance with the regulation EN166.

Skin protection: In case of possible contact with the skin, wear chemical-resistant category II gloves (EN 374), in adequate material, also suitable for direct and prolonged contact (for example, PVC, butyl and fluorinated rubber). The gloves have to be regularly inspected and replaced in case of usury, perforation or contamination.

Body protection: Select the adequate protective media, depending on the activity and exposition (apron, boots, adequate clothes). In particular, in case of potential prolonged exposition, select at least category II clothes. Replace and wash the means of protection at the end of the working time, so as to avoid any transfer of product to the personal clothes.

Respiratory protection: It is recommended to minimize the exposure in case of dust formation, so as to avoid the irritation of the respiratory track. In case of doubt, use a FFP1 category filtering facemask.

Control of environmental exposure: The storage plants have to be equipped with appropriate systems, to avoid the soil and water contamination, in case of leakages or spillages.

9: Physical and Chemical Properties:

For a proper interpretation of the information set out in this section, please refer to the information provided in section 16 of this Data Sheet under heading “Data on intrinsic properties and category approach”.

9.1 – Information on basic physical and chemical properties

Colour:	White
Odour:	Odourless
Melting point/freezing point:	168 - 171°C (REACH dossier - secondary source)
Boiling point or initial boiling point and boiling range:	179.1 °C (ASTM E537/07) 399°C (REACH dossier - secondary source)
Flammability:	not flammable (NF T 20-042:1985) > 200°C (REACH dossier - secondary source)
Lower and upper explosion limit:	not necessary, the substance is not explosive
Flash point:	> 100 °C (ASTM D93/07) > 200°C (REACH dossier - secondary source)
Auto-ignition temperature:	375 °C a 1013 hPa (NFT 20-036) > 400°C (REACH dossier - secondary source)
Decomposition temperature:	425 °C (Dossier REACH) > 170°C (Dossier REACH – secondary source)
pH: below the pH values of the different solutions of tartaric acid (internal method):	
Concentration w/w (%) 1 5 10 20 pH value 2.17 1.65 1.52 1.19 - pH value 2.2 (1470 g/l in water solution @ 25 °C)	
Kinematic viscosity:	not applicable: the substance is a solid
Solubility:	Partition coefficient n-octanol/water (log value): water = 1390 g/l @ 20 °C



	ethanol = 33 g/100 ml @ 25 °C ether = 0.4 g/100 ml @ 25 °C
Partition coefficient n-octanol/water (log value):	log Pow = -1.91 (OECD 107) logKow < 0 (secondary source)
Vapour pressure:	< 5.23·10 ⁻² mPa = < 5.23·10 ⁻⁵ Pa < 3.93·10 ⁻⁷ mmHg a 40°C (EU Method A.4) < 5 Pa a 20 °C (NTF 20-048)
Density and/or relative density:	1.76 g/cm ³
Relative vapour density:	not determined (the substance is solid)
Particle characteristics:	fine powders/coarse granules (OECD 110 Particle Size Distribution / Fibre Length and Diameter Distributions). Particles (fine powders, granules) smaller than 1000 µm

9.2 – Other information

9.2.1. Information with regard to physical hazard classes

- Explosive properties: Not explosive (in the molecule there are no groups that can be associated with explosive properties)
- Flammable solids: The substance was not found to be flammable (EU method A.10.: Flammability (solids))
- Pyrophoric solid: Experience gained from handling the product shows that the substance does not ignite spontaneously when it comes into contact with air at normal temperatures (i.e. the substance is known to be stable at room temperature for extended periods of time (days)).
- Substances and mixtures which emit flammable gases in contact with water: The product is not combustible, does not emit flammable gases in contact with water and does not have pyrophoric properties.
- Oxidizing solids: Not oxidant; in the molecular structure of the substance there are no oxidizing groups, all the oxygen atoms are bonded directly to the carbon or hydrogen and there are also no halogen atoms.
- Organic peroxides: The chemical structure of the substance does not contain peroxide groups.

9.2.2. Other safety characteristics

No other safety characteristics.

10: Stability and Reactivity:

10.1 – Reactivity

The substance presents no limits related to reactivity.

10.2 – Chemical stability

The substance is stable in every ordinary circumstance and under normal conditions of use.

10.3 – Possibility of hazardous reactions

The substance is stable in every ordinary circumstance and under normal conditions of use.

10.4 – Conditions to avoid

Avoid dust formation and exposure to heat sources. Keep separated from oxidizing agents.

10.5 – Incompatible materials

Oxidizing agents, bases, reducers and silver.

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10.6 – Hazardous decomposition products

The substance does not decompose, if used as expected. Among combustion products, carbon monoxide can develop (CO). When the substance decomposes, the smell it emits is similar to the sugar's one.

11: Toxicological Information:

For a proper interpretation of the information set out in this section, please refer to the information provided in section 16 of this Data Sheet under heading "Data on intrinsic properties and category approach".

Animal metabolism:

Experiments on a rabbit show that the tartaric acid absorbed is eliminated through urine, and only to a lesser extent through biliary excretion and/or faeces. Oral administration of 50 mg/kg doses leads to a quick urine excretion, but after increasing doses up to 300 mg/kg, excretion is reduced to 3%. Intramuscular administration of 50 mg/kg doses of tartaric acid also leads to nearly complete urinary excretion, whereas dose increase reduces urine excretion, up to 12%, with 300 mg/kg doses. It has been observed that tartrate administration in a dog, both oral and parenteral, determines a renal excretion similar to that of substances that are not modified in the organism.

Human metabolism:

Some studies on human beings have shown that intravenous and intramuscular administration of tartaric acid determines nearly complete excretion of the compound as such. Oral administration instead shows that 20% of the substance is eliminated as such and the remaining part is metabolized by the intestinal flora.

11.1 – Information on hazards classes as defined in Regulation (EC) No 1272/2008

a) Acute toxicity:

Acute Oral and Dermal Toxicity

Acute toxicity of tartaric acid and its salts has been studied through several tests, carried out mainly through oral and subcutaneous administration. Nearly all data support the absence of a significant acute toxicity for both exposure routes. Such results are observed with high doses that do not lead to a classification, as evidenced by the values of the lethal dose 50 (LD50):

Experimental studies (Tartaric acid)

Acute oral toxicity (rat) LD50 >2000 mg/kg OECD423

Acute dermal toxicity (rat) LD50 >2000 mg/kg OECD402

Other data:

Tartaric acid	LD50 oral rat:	920 mg/kg
Tartaric acid	LD50 oral rat:	> 5000 mg/kg
Tartaric acid	LD50 oral mouse:	4109 mg/kg
Monosodium tartrate	LD50 oral rat:	> 2000 mg/kg
Disodium tartrate	LD50 oral rat:	> 5000 mg/kg
Tartaric acid	LD50 subcutaneous dog:	> 2000 mg/kg
Monosodium tartrate	LD50 subcutaneous cat:	> 2000 mg/kg

Data are considered as conclusive for establishing non-classification of the substance.

Inhalation Toxicity

No data relevant to this hazard class are available.

b) Skin corrosion/skin irritation:

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With a view to evaluation of its irritant potential, tartaric acid has been considered independently of its salts. The acid shows a low pH value (about 2), whereas its salts' values are greater than or equal to 3. On the basis of clinical investigations (data collected from human beings), tartaric acid is considered irritant for skin. Signs of skin irritation have been observed in different workers who handled the substance. The most frequent symptoms in the group of exposed workers were: skin irritation; hands irritation; face and scalp irritation; chronic skin alterations; ulcers and periungueal splits. On the other hand, in vitro and in vivo experimental studies conducted with the substance in the solid state did not show any corrosive or irritant effects.

Based on experimental data, the substance in the solid state is not classified for skin corrosion or irritation effects.

c) Serious eye damage/serious eye irritations:

With a view to evaluation of its potential eye irritant, tartaric acid has been considered independently of its salts. The acid shows a low pH value (about 2), whereas its salts' values are greater than or equal to 3. Potassium bitartrate powder was instilled into the anterior chamber of a rabbit's eye and didn't produce any reaction. On the basis of experimental data deriving from a hygiene/health survey (data collected from human beings), tartaric acid is considered irritant for eyes. Taking into account the extreme pH (equal to 2) of the substance, capable of producing serious eye damage, and in light of the signs of eye irritation observed in a large amount of workers exposed to the substance, tartaric acid is considered a strong eye irritant, capable of causing serious eye injuries.

Moreover, the following experimental study conducted on tartaric acid is available:

Bovine Corneal Opacity and Permeability (BCOP) (OECD 437)

Irritation Parameter - Corneal Opacity Score - Value: 118.765 [Test criterion > 80.1 severe eye irritant]

Based on the evaluation criteria of the test performed, tartaric acid was classified as a severe eye irritant.

Available data are considered conclusive for classification of the substance as Eye Dam. 1; H318 (Causes serious eye damage).

d) Respiratory or skin sensitivity:

No cases of skin or respiratory sensitization have been observed in health surveillance studies on workers exposed to tartaric acid. The workers only showed signs of respiratory tract irritation, attributable to the general dustiness of the work environment. In addition, the following experimental study conducted on tartaric acid is available:

Local Lymph Node Assay (OECD 429) Result: not sensitizing

The available data are considered conclusive for not classifying the substance for these hazard classes.

e) Germ cell mutagenicity:

Tartaric acid has been subjected to different mutagenesis and clastogenesis tests, both in vitro and in vivo. Particularly, tests included in vivo and in vitro chromosome aberration tests in mammals, bacterial reverse mutation tests (Ames test), in vitro DNA repair tests in mammalian cells. No mutagenic or clastogenic activities were shown by the substance in nearly every test, except for a positive result in yeast (*Saccharomyces* D3) and an ambiguous result in a dominant lethal mutation test. Yet, in both cases, repetition of the tests gave negative results. The available data about the tartaric acid's salts also confirm the absence of mutagenicity and clastogenicity for this category of substances. Particularly, (i) a series of bacterial reverse mutation tests and an in vitro chromosome aberration test in mammals showed negative results with potassium hydrogen tartrate (ii) a single negative result in a bacterial reverse mutation tests with sodium hydrogen tartrate; (iii) a negative result in the bacterial reverse mutation tests is available for sodium tartrate which, on the contrary, resulted positive in an in vitro chromosome aberration test in mammals. This positive result was weakened by the absence of clastogenicity recorded in the in vivo micronucleus test carried out both



with single doses first and with repeated administrations afterwards. Below is a short list of data reported in literature. The available data are considered conclusive for establishing non-classification of the substance for this hazard class.

In vitro studies:	
Tartaric acid, OECD Guideline 471 Bacteria reversal test	Negative
Tartaric acid, OECD Guideline 473 Chromosome aberration test in mammals	Negative
Monopotassium Tartrate, OECD Guideline 471 Bacteria reversal test	Negative
In vivo studies:	
Tartaric acid, OECD Guideline 475 Chromosome aberration test on mammals' bone marrow	Negative
Sodium Tartrate, OECD Guideline 474 Micronucleus test on mammals' erythrocytes	Negative

The available data are considered conclusive for establishing non-classification of the substance for this hazard class.

f) Carcinogenicity:

In the available chronic toxicity studies, no cases of tumours were observed. The substance is not classified for this hazard class.

g) Reproductive toxicity:

Tartaric acid has been studied for its reproductive toxicity in rabbits, rats, mice and hamsters. The substance has not affected the parameters relevant to the reproductive activity. Particularly, it has not caused an increase in skeletal anomalies and a reduction in the foetal survival over the control groups. Particularly, a study (EPA OTS 798.4700 on reproductive toxicity and on fertility) assessed the teratogenic effect of tartaric acid on mice. All the animals were observed every day as to their appearance and behaviour, with a particular attention to food consumption and weight variations, in order to exclude any anomaly due to maternal toxicity. On day 17 of gestation, all females underwent a caesarean section, and the number of implantation sites, resorption sites, and of foetuses born alive or dead were recorded. Body weights of the puppies alive were also recorded. The urogenital tract of every female was examined in detail in order to assess its normal anatomy. All foetuses were subjected to assessment as to the presence of congenital anomalies. Administration of tartaric acid (274 mg/kg of body weight) for ten consecutive days (7-15 day of gestation) did not determine any variation on the sexual function, on fertility and on development of the offspring. Moreover, in another study, the administration of tartaric acid (215 mg/kg of body weight) to rabbit females (day of gestation not reported), for 13 consecutive days, did not have any effect on implantation, on maternal or foetal survival. The number of anomalies observed both in the soft and skeletal tissues of the test groups did not differ from the anomalies occurring spontaneously during controls. The available data are considered conclusive for establishing non-classification of the substance for this hazard class.

h) Specific target organ toxicity (STOT SE) – single exposure:

No organ damages were observed after single exposure to the substance.

i) Specific target organ toxicity (STOT RE) – repeated exposure:

Toxicity after repeated doses of tartaric acid and its salts has been assessed through oral route. Administration of sodium tartrate following a 2-year diet with doses of 25600, 42240, 60160 and 76800 ppm (equivalent to a level of edible tartaric acid of 20000, 33000, 47000 or 60000 ppm, respectively), did not cause adverse effects. Particularly, assessment of animal blood and urine parameters did not reveal any reaction to the treatment. Similarly, in relation to such treatment no



necroscopic changes or variations in the weight of the organs of rats, sacrificed after 104 weeks, were observed. Histological examination of the tissues did not show any evidence of toxicity or tumour induction that could be attributed to the treatment with sodium tartrate. Moreover, another study administering tartaric acid to rats through a 104-week diet showed a low toxicity degree of the substance. No significant variations of the examined parameters such as necroscopic changes, weight variations and variations in food consumption were observed, and no case of mortality was reported. The available data are considered conclusive for establishing non-classification of the substance for this hazard class.

j) Aspiration hazard:

No data relevant to this hazard class are available. Yet, on the basis of the physicochemical properties of the substance, such hazard is not expected. Hence, classification of the substance for this hazard is excluded.

11.2 – Information on other hazards

11.2.1. Endocrine disrupting properties:

Tartaric acid does not have endocrine disruptive properties. It is not listed in the most important databases of substances with endocrine disruptive properties.

11.2.2. Other information:

No further toxicological information is available.

12: Ecological Considerations:

For a proper interpretation of the information set out in this section, please refer to the information provided in section 16 of this Data Sheet under heading “Data on intrinsic properties and category approach”.

12.1 – Toxicity

Considering the ecotoxicological data and the absence of bioaccumulation potential, the substance is not dangerous for the aquatic environment. Here below the main data concerning aquatic toxicity:

Short-term effects on fish:

OECD 203 Fish, Acute Toxicity Test (tartaric acid)

LC50 (96h): >100 mg/L

Short-term toxicity to aquatic invertebrates:

OECD 202: Daphnia sp. Acute Immobilisation Test (tartaric acid)

EC50 (48h): 93.31 mg/l

Short-term toxicity to aquatic algae and aquatic plants:

OECD 201: Alga Growth Inhibition Test (tartaric acid)

EC50 - Alga - 51.4 mg/l 72 h

NOEC - Alga - 3.125 mg/l 72h

Microorganisms toxicity:

OECD 209: Activated Sludge, Respiration Inhibition Test (tartaric acid)

EC50 Activated Sludge >1000 mg/l 3 h

Long-term toxicity to fish:

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NOEC (30 days): 43.141 g/L (estimated on tartaric acid))

Long-term effects on aquatic invertebrates:

NOEC 11.88 g/L (estimated on tartaric acid)

12.2 – Persistence and degradability

Degradability:

Several studies in the scientific literature have investigated biodegradability of tartaric acid in water with regulated methods, whereas just one study is available for sodium tartrate. All results confirm biodegradability of such substances, with the exception of a study carried out by Sharma et al reporting a BOD5/COD ratio slightly less than 0,5 (cut-off value between biodegradability and non-biodegradability in accordance with CLP regulation) for tartaric acid. On the whole, such a low value is considered to be due to experimental variability. Below is a short list of some data obtained from the tests carried out on tartaric acid. Readily biodegradable.

OECD guidelines 301 C (Determination of timely biodegradability) ESSAY M.I.T.I. (C.4-F Method)

76% after 14 days (O₂ consumotion)

100% after 14 days (TOC total organic carbon removal)

100% after 14 days (Tested material) Readily biodegradable

OECD guidelines 301 C (Determination of timely biodegradability) ESSAY M.I.T.I. (C.4-F Method)

75% 14 days (O₂ consumotion)

92% 14 days (TOC total organic carbon removal)

100% 14 days (Tested material) Readily biodegradable

Degradation - biochemical oxygen demand (BOD₅)

Readily biodegradable.

Hydrolysis	Hydrolytically stable	OECD 111
Biodegradation (water)	85% (28 days)	OECD 306
Biodegradation (soil)	DT50 = 9.6 h	OECD 307

12.3 – Bioaccumulative potential

Tartaric acid is an organic acid naturally present in several plants and particularly in grapes, abundant both in its free form and in the form of salt. No bioaccumulation data are available on the relevant aquatic species. Yet, with a measured value of octanol-water partition coefficient (log K_{ow}) < 3, the substance is not expected to be bioaccumulative.

12.4 – Mobility in soil

No data on the substance's mobility in soil are available. Such data were not generated, as direct or indirect exposure in soil is unlikely to occur, since the expected working conditions assure the absence of environmental release by the substance. Moreover, according to column 2 of Annex VIII to REACH Regulation, the study does not need to be conducted, because tartaric acid and its salts have a low potential for absorption, as confirmed by a low octanol-water partition coefficient.

12.5 – Results of PBT and vPvB assessment

The substance does not meet the criteria for PBT and vPvB, set out in the Annex XIII of REACH Regulation.

12.6 – Endocrine disrupting properties

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Tartaric acid does not have endocrine disruptive properties. It is not listed in the most important databases of substances with endocrine disruptive properties.

12.7 – Other adverse effects

No further relevant information is available.

13: Disposal considerations:

13.1 – Waste treatment methods.

Product residues have to be considered special hazardous waste. Disposal have to be performed through an authorized waste management firm, in compliance with national and local regulations. If possible, employ an incineration plant.

Contaminated packaging and containers have to be recovered or disposed of, in compliance with national waste management regulations. They have to be sent to a company specialized in incineration, recycling or landfilling. Containers have to be cleaned by washing them with water, which will be destined to waste water treatment.

14: Transport Information:

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1 – UN number

Information not relevant: the substance is not classified as dangerous for transport.

14.2 – Proper Shipping Name

Information not relevant: the substance is not classified as dangerous for transport.

14.3 – Transport hazard class(es)

Information not relevant: the substance is not classified as dangerous for transport.

14.4 – Packing group

Information not relevant: the substance is not classified as dangerous for transport.

14.5 – Environmental hazards

Information not relevant: the substance is not classified as dangerous for transport.

14.6 – Special precautions for user

Information not relevant: the substance is not classified as dangerous for transport.

14.7 – Maritime transport in bulk according to IMO instruments

Information not relevant: the substance is not classified as dangerous for transport.

15: Regulatory Information:

15.1 – Safety, health and environmental national regulations specific for the product

REACH Regulation CE n. 1907/2006 and s.m.i.:

Product not contained in the list of substances of very high concern (SVHC), applicants for authorization. Product is not subject to restriction.

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Other EU regulations and national transpositions:

Chemical dangerous agent, according to Dir. 98/24/CE and Chapter I, Title IX of Legislative Decree 81/08 and s.m.i.; chemical agent that is not subject to SEVESO regulation; chemical agent that is not subject to Rotterdam Convention.

Check the following provisions:

Regulation N. 10/2011 on plastic materials and articles intended to come into contact with food. Tartaric acid is present in the union list of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids
Directive 2007/42/CE relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs. Tartaric acid is present in the list of substances authorised in the manufacture of regenerated cellulose film.

15.2 – Chemical safety assessment

A chemical safety assessment has been performed for this substance, as provided for in Regulation (EC) 1907/2006.

16: Other Information:

Data on intrinsic properties and category approach:

Data on tartaric acid intrinsic properties are consistent with the information contained in the registration dossier of the substance in compliance with REACH Regulations. Particularly, they derive from the information worked out for the specific category of tartaric acid and its salts. Such category is based on the hypothesis that all members represent the different ionized forms of tartaric acid. The main prerequisite is that the presence of sodium, potassium and calcium in the molecule is a non-significant one with respect to the intrinsic properties of tartaric acid. By evaluating the physicochemical behaviour of its salts, it is assumed that the latter do not behave differently from the acid when in watery solution and under specific pH conditions. This is the why some properties of the salts (measured or expressed in aqueous environment) can be directly transferred by use of “read-across” to the “parent” acid and vice versa. In relation to irritation/corrosion properties, the acid is considered separately from its salts. When considering the stereochemistry of the substances in the category, in the absence of biological effects caused by stereoselective interactions with chiral “targets”, data relevant to a specific molecule stereoform can be used to predict the same properties to their enantiomers and diastereoisomers by the read-across approach.

Indications on the training:

Provide appointed staff, potentially exposed to the substance, with adequate training, on the basis of the contents of this Safety Data Sheet.

Abbreviations and acronyms:

DL50: Lethal Dose 50;

CL50: Lethal Concentration 50; EC50: Effective Concentration 50;

NOEC: No observed effect concentration; DT50: Half-life in the soil.

Bibliography:

Reference to the REACH registration dossier of tartaric acid.

The information contained in this data sheet is, to the best of our knowledge, true and accurate, but any recommendations or suggestions which may be made are without guarantee, since the

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