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SIRET: 338 502 941 00044 / NAF: 2059Z / N° TVA: FR24 338 502 941



FICHE TECHNIQUE

tri-POTASSIUM CITRATE Pur, E332 (règlement 231/2012) Réf : 24112

 $\begin{array}{lll} N^{\circ} \text{ C.A.S. \#} & [\ 6100\text{-}05\text{-}6] \\ \text{Formule:} & \text{C}_{6}\text{H}_{5}\text{K}_{3}\text{O7} \text{ , H}_{2}\text{O} \\ \text{pH à 5 \%:} & 7,5-9,0 \\ \text{Solubilité à 25°C:} & 606 \text{ g/l} \end{array}$

Teneur: 99 % mini Perte au séchage: 4,0 à 6,0 %

Métaux lourds: 5 ppm maxi Sulfates: 100 ppm maxi Chlorures: 15 ppm maxi Sodium: 0,3 % maxi Oxalate: 100 ppm maxi Arsenic: 1 ppm maxi Plomb: 0,5 ppm maxi Mercure: 0,5 ppm maxi

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Jungbunzlauer

Product Information

Tripotassium Citrate

General Information

Tripotassium citrate monohydrate (TPC) is the common tribasic potassium salt of citric acid, also known as potassium citrate. It is produced by complete neutralization of citric acid with a high purity potassium source and subsequent crystallization.

TPC is used in foods, beverages, personal care and technical applications as buffering, sequestering or emulsifying agent. It usually replaces trisodium citrate whenever low sodium content is desired. In pharmaceuticals it is used as potassium source and as active ingredient (systemic alkalizer) e.g. to treat urinary duct stones. When added to oral care products, tripotassium citrate is the active ingredient to reduce the sensitivity of the teeth.

Chemical Data

Chem. Nomenclature: Tripotassium 2-hydroxyproprane- 1,2,3-tricarboxylate monohydrate

Synonym Potassium Citrate

 $\begin{array}{lll} \text{Molecular formula} & C_6H_5O_7K_3, H_2O \\ \text{Molecular weight} & 324.4 \text{ g/mol} \\ \text{pH-value (5 \%)} & 7.5 - 9.0 \\ \text{Bulk density} & 950 - 1200 \text{ g/l} \\ \text{Solubility} & 606 \text{ g/l (25°C)} \\ \text{REACH No.} & 01-2119457580-38 \\ \end{array}$

EC No. 212-755-5 CAS No. 6100-05-6 E-No. E 332

Specification

TPC is supplied in accordance with the requirements of the Food Chemical Codex (FCC), the US Pharmacopeia (USP), the European Pharmacopeia (Ph.Eur.) and the Commission Regulation (EU) No. 231/2012 always in their latest versions.

<u>Parameters</u>	Jungbunzlauer Limits
Characteristics	conforms
Identification	conforms
Acidity or alkalinity	conforms
Water (Karl Fischer)	4.0 - 6.0 %
Loss on drying (180°C)	4.0 - 6.0 %
Tartrate	conforms
Heavy metal as lead	max. 5 mg/kg
Organic volatile impurities	conforms
Appearance of solution	conforms
Readily carbonisable substances	conforms
Chloride max.	15 mg/kg
Oxalic acid / oxalate max.	100 mg/kg

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Sulphate max.	100 mg/kg
Sodium max.	0.3 %
pH-value (5 % solution)	7.5 - 9.0
Arsenic max.	1 mg/kg
Lead max.	0.5 mg/kg
Mercury max.	0.5 mg/kg
Potassium	35.6 – 36.2 %
Assay	99.0 – 100.5 %

Characteristics

Tripotassium citrate occurs as transparent crystals or a white, granular powder. It is an odourless substance with a cooling, salty taste. It is slightly deliquescent when exposed to moist air, freely soluble in water and almost insoluble in ethanol (96%). In contrary to other potassium salts, it is less bitter and thus can be used at higher concentration levels.

Tripotassium citrate is a non-toxic, slightly alkaline salt with low reactivity. It is chemically stable if stored at ambient temperatures. In its monohydrate form it is very hygroscopic and must be protected from exposure to humidity. Care must be taken not to expose tripotassium citrate monohydrate to high pressure during transport and storage as this may result in caking. TPC is fully biodegradable and can be disposed of with regular waste or sewage.

Granulation

Туре	Particle	Limits
Coarse G 2040	> 2.00 mm (on 10 Mesh)	max. 10 %
	< 0.40 mm (through 40 Mesh)	max. 10 %
Medium M 1201	> 1.20 mm (on 16 Mesh)	max. 1 %
	< 0.15 mm (through 100 Mesh)	max. 10 %
Fine F 6001	> 0.60 mm (on 30 Mesh)	max. 10 %
	< 0.20 mm (through 70 Mesh)	max. 15 %

Legal Aspects

In Europe, tripotassium citrate is listed as a generally permitted food additive (E 332) and may be added to all foodstuffs, following the "quantum satis" principle as regulated in EU Regulation (EC) No. 1333/2008 (Annex 2), as long as no special regulation restricts the use. In addition to existing national allowances in some countries, tripotassium citrate is on the positive list of the EU Regulation (EC) No. 1925/2006 on food fortification and is allowed in food supplements (Directive 2002/46/EC). It is listed as mineral salt in the EU Regulation (EC) No. 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.

The US Food and Drug Administration (FDA) affirmed tripotassium citrate as generally recognized as safe (GRAS) food substance and permitted the use in food with no limitation other than current good manufacturing practice (21 CFR § 184.1625).

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Our API grade is produced according to GMP for active substances. It is registered with the US FDA since May 2000 with Drug Master File 14847 Type II and at the EDQM since October 2012 with a Certificate of Suitability (CEP).

Packaging and Storage

Tripotassium citrate is very hygroscopic. Therefore, adverse storage conditions should be strictly avoided to prevent caking.

storage conditions: Temperature < 40°C Relative humidity < 60 %