



Specification

| Concerning Product: | |
|---|--|
| Article number | 4468024NPEL |
| Trade name / designation / denomination | Zinkgluconat, EP |
| CAS number | 4468-02-4 |
| Other names / synonyms | •(2R,3S,4R,5R)-2,3,4,5,6-pentahydroxyhexanoic acid; zinc; •Zinc gluconate; •bis(D-gluconato-O1,O2)zinc; |
| EC number | 224-736-9 |
| Customs tariff number / CN code / TARIC | 29181600 |
| Molecular weight [g / mol] | 457.71956 |
| Formula | C ₁₂ H ₂₄ O ₁₄ Zn |

| Parameter | Specification | Unit |
|------------------------------|--|------|
| Organoleptic test | | |
| Appearance of solution | complies | |
| Appearance | white or almost white, hygroscopic, crystalline powder | |
| Physical parameter | | |
| Loss on drying | ≤ 12 | % |
| Solubility | soluble in water, practically insoluble in anhydrous ethanol and in methylene chloride | |
| Identity | | |
| Assay | (anhydrous substance) 98,0 – 102,0 | % |
| Identification | A, B: complies | |
| Impurities | | |
| Heavy Metals (as Pb) | ≤ 10 | ppm |
| Sulphates (SO ₄) | ≤ 500 | ppm |
| Residual Solvents | | |
| Residual solvents | The above mentioned product complies with note for guidance on impurities regarding residual solvents (ICH Topic Q3C (R5), EMA/CHMP/ICH/82260/2006, CMPM/ICH/283/95 and CPMP/ICH/1940/00). | |
| Elemental Impurities | | |
| Arsenic (As) | ≤ 3 | ppm |
| Cadmium (Cd) | ≤ 2 | ppm |
| Chlorides (Cl) | ≤ 500 | ppm |
| Mercury (Hg) | ≤ 0,1 | ppm |
| Lead (Pb) | ≤ 3 | ppm |
| Zinc (Zn) | as dihydrate: 12,90 – 13,56 | % |
| Nutritional data | | |
| Calories | 1006 | kJ |
| Calories | 240 | kcal |
| Sugar | reaction on Sucrose and reducing sugars: confirmed | |

| Microbiological data | | |
|-----------------------------|------------------------|-------|
| Escherichia Coli. | not detectable in 1 g | |
| Salmonella | not detectable in 25 g | |
| Total Plate Count | ≤ 1000 | CFU/g |
| Yeast and Mould | ≤ 100 | CFU/g |

Regulatory information:

Allergens statement: According to Annex II of Regulation (EU) No **1169/2011** of the European Parliament and of the Council of 25th October 2011 and its amendment (EU) No **78/2014** on substances or products the above mentioned product does NOT cause allergies or intolerances and does NOT contain any allergens which have to be labelled according to these regulations.

BSE/TSE statement: Risk of BSE/TSE contamination can be excluded.

GMO statement: Genetic engineering:

For the above mentioned product there is no obligation of g.m.o. labelling as defined by the Regulations (EC) No **1829/2003** and **1830/2003** of the European Parliament and the Council of 22nd September 2003.

Irradiated Status: Product has not been treated with ionizing radiation and does not contain any ingredients which have been treated with ionizing radiation.

Nanoparticles: The product does not contain any raw materials, ingredients or additives in nanoparticle size as per definition of Regulation (EU) No **1169/2011** respectively Regulation (EU) No **2015/228**.

Supplemental information:

Shelf life: 24 month

Derivation: synthetic, (mineral,) vegetable: maize

Note: Traceability

According to Regulation (EC) No **178/2002** the traceability of the raw materials for the product is guaranteed one step backwards and of produced batches one step forward. All instructions, which are necessary to take these steps, are implemented in the Quality manual and management system according to IFS and BRC.

Storage conditions: Protect from light and store cool and dry in well-closed original packaging. The temperature should not exceed 25 °C.

The primary packaging of the above mentioned product is suitable for food

Regional origin: CN

Usage: The product is suitable for a vegetarian nutrition.

The product is suitable for a vegan nutrition.

The product is suitable for lactose intolerance diet.

The product is suitable for people with coeliac disease and sprue.

The product is in compliance with Jewish dietary laws.

The product is in compliance with Islamic dietary laws.

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 19. Feb. 2020

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