

93695-POTASSIUM IODIDE**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1. Identification of the substance or preparation**

Name: Potassium Iodide

Bulk code: 93695

Internal code: 405647

1.2. Synonyms

Potassium iodide; Potassium iodure; Kalii iodidum.

2. DESCRIPTION

Appearance: Crystalline powder.

Colour: White.

Origin: Synthetic (Iodine (mineral origin) and Potassium Hydroxide, 45-50% solution (mineral origin))

Geographical origin: France

3. COMPOSITION/INFORMATION ON COMPONENTS

Formula: KI

CAS: 7681-11-0

EINECS: 231-659-4

Molecular weight: 166 g/mol

INCI: Potassium iodide

Composition: The Potassium content would be 23.5% approx. The percentage has been calculated taking into account the molecular weight of KI (166) i K (39,09). Based on the assay of potassium iodide, the product has an iodide content between 75.68 and 76.83%.

In accordance with EU Regulation 1169/2011, amending EU Regulation 1924/2006 and EU Regulation 1925/2006, the product is Potassium Iodide and its content (in %) in this product is 100%.

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: The product is soluble in water, alcohol, acetone, glycerol and glycol.

Slightly hygroscopic.

5. PROPERTIES/USES

Excipient for pharmaceutical use.

Oral use.

Not suitable for the manufacture of food supplements or foods.

93695-POTASSIUM IODIDE**6. DOSAGE**

No information available.

7. REMARKS**STORAGE:**

Store in a cool, dry, well-ventilated place away from sunlight, in a tightly closed container and away from oxidants and heat and moisture sources. Potassium iodide can turn yellow in prolonged exposure to air due to the release of iodine, and small amounts of iodate may also form.

The documentation available related to the product's regulatory compliance is included below.

BSE/TSE:

The product does not contain and is not a derivative of a specific risk material as defined in the European Commission Directive and its amendments and therefore is compliant with EU legislation concerning the risk of transmitting spongiform encephalopathy (TSE).

GMOs:

The following Community rules have been published in the Official Journal of the European Union:

- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.
- Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

This product has not been genetically modified and thus there is no requirement to label GMOs as defined above.

CMR substances:

The product is not considered a carcinogenic, mutagenic or reprotoxic substance.

NANOMATERIALS:

According to the definition of 'Nanomaterials' in Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 (amending Commission Regulation (EC) No 1924/2006 and Commission Regulation (EC) 1925/2006) on the provision of food information to consumers, nanomaterials are not used in the manufacture, formulation or packaging of this product.

IRRADIATION:

According to Directives 1992/2/EC and 1999/3/EC, the product has not been made with irradiated/ionised raw material and the product has not undergone irradiation/ionisation.

IMPURITIES/CONTAMINANTS:

The product does not contain any preservatives, benzoates, silicones, ethylene oxide, asbestos, plant hormones or growth promoters, artificial colorants, artificial flavours, yeast, starch, sugars,

93695-POTASSIUM IODIDE

maltodextrins, lecithin, alcohol, spices, bioflavonoids, talc, royal jelly, bee pollen, kiwi fruits, fava beans, stabilizers, thickeners, emulsifiers, aromatic substances, phenylalanine, moisturizers / humectants.

The product is free of:

- Latex
- Aflatoxins and mycotoxins
- DEHP and DINP phthalates
- benzopyrene, PAHs.

PCBs and melamine: This product is in accordance and meets with the Commission Regulation (EU) No. 2023/915 as regards the maximum levels of the contaminants Ochratoxin A, non-dioxin-like PCBs and melamine in foodstuffs.

The source raw material and the material from which the product is obtained does not contain pyrrolizidine alkaloids.

ELEMENTAL IMPURITIES:

Elemental impurity (ICH Q3D)	Class	Likely to be present		If known, Expected Concentration (ppm)	Analytical Method Used	Comments regarding source of information
		Yes	No			
Arsenic	As	1	X			
Lead	Pb	1	X	< 1 ppm	ICP-OES	Tested twice a year
Cadmium	Cd	1	X	< 1 ppm	ICP-OES	Tested twice a year
Mercury	Hg	1	X			
Cobalt	Co	2A	X			
Nickel	Ni	2A	X	< 2 ppm	ICP-OES	Tested twice a year
Vanadium	V	2A	X			
Silver	Ag	2B	X			
Gold	Au	2B	X			
Thallium	Tl	2B	X			
Palladium	Pd	2B	X			
Platinum	Pt	2B	X			
Iridium	Ir	2B	X			
Osmium	Os	2B	X			
Rhodium	Rh	2B	X			
Ruthenium	Ru	2B	X			
Selenium	Se	2B	X			
Molybdenum	Mo	3	X			
Antimony	Sb	3	X			
Barium	Ba	3	X			
Chromium	Cr	3	X	< 1 ppm	ICP-OES	Tested twice a year
Copper	Cu	3	X	< 2 ppm	ICP-OES	Tested twice a year
Tin	Sn	3	X			
Lithium	Li	3	X			



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Type of document:

TECHNICAL DATA SHEET

Review date:

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93695-POTASSIUM IODIDE

PESTICIDES:

Based on knowledge about the production process, starting materials and equipment used, potential pesticide residues in the product are compliant with European legislation on pesticide residues (EC Regulation No 396/2005 and its amendments). However, the content thereof is not routinely analysed.

RESIDUAL SOLVENTS:

Solvents are not used in the manufacturing process. The product is free of residual solvents and fulfill the requirements for residual solvents according to guides CPMP/ICH/283/95-Q3C(R4) and EMA/CHMP/ICH/82260/2006-Q3C(R6).

The product is compliant with:

- Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.
- Directive 2010/59/EU of 26 August 2010 amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to extraction solvents used in the production of foodstuffs and food ingredients.

ALLERGENS

- **Food allergens:** The product does not contain, derive from, or could be cross contaminated with any of the food allergens listed in Regulation (EU) No 1169/2011 amending Commission Regulation (EC) No 1924/2006 and Regulation (EC) No 1925/2006. The product is gluten free.

HALAL:

The product does not have a HALAL certificate; however, it is free of alcohol and hormonal substances.

VEGAN/VEGETARIAN:

The product is suitable for vegan/vegetarian use.

WADA:

The product is not a doping substance nor a combination of doping substances. The product has not been manufactured from doping substances.

TESTED ON ANIMALS:

The product has not been tested on animals.

REACH:

01-2119966161-40-0000