



Specification

Concerning Product:	
Article number	7695912VEU
Trade name / designation / denomination	Vitamin E (DL-alpha-Tocopheryl Acetate) EP/USP
CAS number	7695-91-2
Other names / synonyms	•3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate; •Tocopheryl acetate; •all- <i>rac</i> -α-tocopheryl acetate;
EC number	231-710-0
Molecular weight [g / mol]	472,57
Formula	C ₃₁ H ₅₂ O ₃

Parameter	Specification	Unit
Organoleptic test		
Appearance	viscous, light yellow oil	
Physical parameter		
Acidity/Alkalinity	must comply	
Specific Optical Rotation	-0,01 – +0,01	°
Solubility	soluble in hydrocarbons, alcohols, fats and oils; insoluble in water	
Identity		
Assay	(1 International Unit (I.U.) = 1 mg Vitamin E-Acetate) 98,0 – 102,0	%
Identification	must comply	
Impurities		
Heavy Metals (as Pb)	* ≤ 10	ppm
Related substances	Any other impurity ≤ 0,25	%
Related substances	Impurity A: ≤ 0,5	%
Related substances	Impurity B: ≤ 1,5	%
Related substances	Impurity C: ≤ 0,5	%
Related substances	Impurity D + E: ≤ 1,0	%
Related substances	Total impurities ≤ 2,5	%
Residual Solvents		
Heptane	* (Residual solvent class 3) ≤ 0,5	mg/kg
Elemental Impurities		
Arsenic (As)	* ≤ 1,0	ppm
Cadmium (Cd)	* ≤ 1,0	ppm
Mercury (Hg)	* ≤ 0,1	ppm
Lead (Pb)	* ≤ 2,0	ppm
Zinc (Zn)	* ≤ 10	ppm
Organic volatile impurities		
Methanol	* (Residual solvent class 2) ≤ 3000	mg/kg
Microbiological data		
Aerobic microorganisms	Gesamtzahl lebensfähiger aerober Organismen / Total viable aerobic count ≤ 2000	CFU/g
Escherichia Coli.	neg. in 1 g	CFU/g
Salmonella	neg. in 25 g	
Yeast and Mould	≤ 200	CFU/g

Annotation:

* ensured by quality assurance measures and therefore tested randomly only

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

Lactose Status: The product is suitable for lactose intolerance diet

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**.

Vegan Status: Product is suitable for vegetarian, vegan or coeliac diets (Gluten <= 20 ppm)

Supplemental information:

Shelf life: 3 Jahre / 3 years

Derivation: synthetisch / synthetic

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.

The product contains no animal ingredients

The product contains no palm based components

This material is Kosher and Halal Certified.

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

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 18. Nov. 2024

LF-Basis: 1 (2021-11-04)

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