

ASTRON CHEMICALS S.A.
Tax-No. EL094468327
Thesis Kirillos

19300 ASPROPYRGOS

Ελλάδα

2025-01-17
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Certificate No 2639

Hr. Dr. Florian Wildschek
ENT/QA
florian.wildschek@basf.com

Inspection Certificate 3.1 according to EN 10204

Vitamin E Acetate 98%	Material	50315393
25KG Plastic drums	Order	3387536318 000050
Purchase order/Customer material	Delivery	3539140297 000010
2410321	Batch	28835947G0
50315393	Batch/Qty	25.000 KG
	Total	25.000 KG
	Transport	DACHSER SG

Test Parameter	Requirements	UoM	Results
Assay all-rac-alpha-tocopheryl acetat (GC) (PhEur)	Min.: 98.0 Max.: 102.0	g/100g	98.9
Assay all-rac-alpha-tocopherylacet- at (GC) (USP)	Min.: 98.0 Max.: 102.0	g/100g	99.1
Vitamin E activity (calc.)** (USP)	Min.: 980 Max.: 1020	I.U./g	991
Vitamin E activity calc. as mg/g RRR-alpha-Tocopherol**			451
Appearance	viscous, light yellow oil		conforms
Identification (GC) (Retention Time)	must conform		conforms
Identification (optical rotation)* (USP)	must conform (-0,01 bis 0,01°)		conforms
Related substances (Impurity A)	Max.: 0.5	Area-%	<0.1
Related substances (Impurity B)	Max.: 1.5	Area-%	<0.1

The above-mentioned data describes the relevant parameters of the product at the time of issuing this certificate of analysis (CoA). The data is controlled at regular intervals as part of our quality assurance program and is provided for reference only. The contractually agreed quality of the product at the time of passing of risk is exclusively determined by our product specification. Unless specifically agreed by the Parties in writing signed by authorized representatives, no suitability for a particular use shall be presumed or implied based on the CoA and the customer is solely responsible for determining and verifying the suitability of the use of the product for any purpose.

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Test Parameter	Requirements	UoM	Results
Related substances (Impurity C)	Max.: 0.5	Area-%	0.2
Related substances (sum of impurity D and E)	Max.: 1.0	Area-%	0.2
Related substances (any other impurity)	any other impurity max. 0.25 Area-%		conforms
Related substances (total impurities)	Max.: 2.5	Area-%	0.4
Optical rotation (Ph.Eur.)	Min.: -0.01 Max.: +0.01	degree	+0.00
Acidity	must conform		conforms
Lead *	must conform (max.0, 5mg/kg)		conforms
Cadmium *	must conform (max.0, 5mg/kg)		conforms
Mercury *	must conform (max.0, 1mg/kg)		conforms
Arsenic *	must conform (max.1mg/kg)		conforms
Zinc *	must conform (max. 10mg/kg)		conforms

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Test Parameter	Requirements	UoM	Results
Residual solvent * methanol	must conform (max.3000mg/kg)		conforms
Residual solvent * heptane	must conform (max.0, 5g/100g)		conforms

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* test verified on random samples

** Biological activity and equivalence: 1 mg all-rac-alpha-tocopheryl acetate = 0.455 mg RRR-alpha-tocopherol = 1 IU Vitamin E - e.g., 980 mg/g all-rac-alpha-tocopheryl acetate is equal to 446 mg/g RRR-alpha-tocopherol and 1020 mg/g all-rac-alpha-tocopheryl acetate is equal to 464 mg/g RRR-alpha-tocopherol. The calculated Vitamin E activity (in mg/g RRR-alpha-tocopherol) will be displayed on the CoA. (Please notice, in certain countries/ regions the previous conversion factor may remain: 1 IU Vitamin E = 1 mg all-rac-alpha-tocopheryl acetate = 0.671 mg RRR-alpha-tocopherol).

The product complies with the specification requirements stipulated in the current monographs:

"all-rac-alpha-tocopheryl acetate" of Ph.Eur.11th ed.

"all-rac-alpha-tocopheryl acetate" of FCC 13th ed.

"Vitamin E" of USP-NF 2024, Issue 1

Manufacturer: BASF SE

Carl-Bosch-Str.38
67056 Ludwigshafen
Germany

QC-Reference-No.

24C06967

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Production date (YYYY-MM-DD) 2024-06-04

Release date (YYYY-MM-DD) 2024-07-04

Retest date (YYYY-MM-DD) 2027-06-04

BASF SE

Quality Assurance - Release

sig. Hr. König

QA-Representative

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