

Astron Chemicals S.A.
Tax-No. EL094468327
Thesis Kirilo

19300 Aspropyrgos

Ελλάδα

2023-08-25
Page 1 of 5

Certificate No 1397

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

Inspection Certificate 3.1 according to EN 10204

Vitamin E Acetate 98%

25KG Plastic drums

Purchase order/Customer material

2310304

50315393

Material	50315393
Order	3386696888 000010
Delivery	3197399044 000010
Lot	13425924U0
Lot/Qty	1800.000 KG
Total	1800.000 KG
Transport	MF2D7813 FTJK118

Test Parameter	Requirements	UoM	Results
Assay all-rac-alpha-tocopheryl acetat (GC) (PhEur)	Min.: 98.0 Max.: 102.0	g/100g	99.5
Assay all-rac-alpha-tocopherylacet- at (GC) USP	Min.: 98.0 Max.: 102.0	g/100g	99.6
Vitamin E activity (calc.)** (USP)	Min.: 980 Max.: 1020	I.U./g	996
Vitamin E activity calc. as mg/g RRR-alpha-Tocopherol**			453
Appearance	viscous, light yellow oil		conforms
Identification (GC) (Retention Time)	must conform		conforms
Related substances (Impurity A)	Max.: 0.5	Area-%	<0.1
Related substances (Impurity B)	Max.: 1.5	Area-%	<0.1
Related substances (Impurity C)	Max.: 0.5	Area-%	<0.1

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Test Parameter	Requirements	UoM	Results
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-%	0.2
Optical rotation	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
Heavy metals *	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 2023, Issue 1

Manufacturer: BASF SE

Carl-Bosch-Str.38
67056 Ludwigshafen
Germany

QC-Reference-No.

23C05653

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Production date (YYYY-MM-DD) 2023-05-19

Release date (YYYY-MM-DD) 2023-06-28

Retest date (YYYY-MM-DD) 2026-05-18

BASF SE

Quality Assurance - Release

sig. Hr. König

QA-Representative

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