



2021-06-21 ENT/OQA Hr. Dr. Florian Wildschek florian.wildschek@basf.com Certificate No 5117 Page 1 of 5

Inspection Certificate 3.1 according to EN 10204

Vitamin E Acetate 98% Material 50315393 Order 3384453536 000010 25KG Plastic drums Delivery 3194684034 000010 Purchase Order/Customer Product# Lot 04243575L0 2110103 Lot/Qty 1200.000 KG 000000000050315393 Total 1200.000 KG Transport F2H25014 QAFB774

Test Parameter	Requirements	UoM	Results
Assay all-rac-alpha-tocopheryl acetat (GC) (PhEur)	Min.: 98.0 Max.: 102.0	g/100g	99.8
Assay all-rac-alpha-tocopherylacet- at (GC) USP	Min.: 98.0 Max.: 102.0	g/100g	99.5
Vitamin E activity (calc.)** (USP/FCC)	Min.: 980 Max.: 1020	I.U./g	995
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

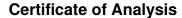


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Test Parameter	Requirements	UoM	Results
Related substances (sum of impurity D and E)	Max.: 1.0	Area-%	0.2
Related substances (any other impurity)	any other impurity max. 0.25 Area -%		conforms
Related substances (total impurities)	Max.: 2.5	Area-%	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	1)	conforms
Zinc *	must conform (max.:10mg/	kg)	conforms
Heavy metals *	must conform (max.10mg/k	ag)	conforms







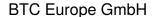
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Test Parameter	Requirements	UoM	Results
Residual solvent * methanol	must conform (max.3000mg/kg)		conforms
Residual solvent * heptane	must conform (max.0,5g/100g)		conforms







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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 meets the specifications of following monographs:

"all-rac-alpha-tocopheryl acetate" of Ph.Eur.10th ed.
"all-rac-alpha-tocopheryl acetate" of FCC 12th ed.
"Vitamin E" of USP-NF 2021, Issue 1
"Tocopheryl Acetate" IP 2018

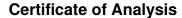
Manufacturer: BASF SE

Carl-Bosch-Str.38 67056 Ludwigshafen

Germany

QC-Reference-No.

21C05926







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 Lot/Qty
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 00000000050315393
 Total
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 Transport
 F2H25014 QAFB774

Production date (YYYY-MM-DD) 2021-05-14

Release date (YYYY-MM-DD) 2021-05-28

Retest date (YYYY-MM-DD) 2024-05-13

BASF SE Quality Assurance - Release sig. Hr. König QA-Representative