

2021-06-21  
ENT/OQA  
Hr. Dr. Florian Wildschek  
florian.wildschek@basf.com  
Certificate No 5117  
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**Inspection Certificate 3.1 according to EN 10204**

Vitamin E Acetate 98%

25KG Plastic drums

Purchase Order/Customer Product#

2110103

00000000050315393

Material	50315393
Order	3384453536 000010
Delivery	3194684034 000010
Lot	04243575L0
Lot/Qty	1200.000 KG
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

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom.

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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 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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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

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