

DL-A-TOCOPHERYL ACETATE



Coversheet for Certificate of Analysis

Productcode : 0420085
Lot No. : UT22110348
Analysis No. : L32485

CfC Number : 05093486
Articlecode : 0420085301
Sales Name : 5 KG PE PAIL DL-A-TOCOPHERYL ACETATE
Manufacturing Date : 16-OCT-2022
Best Use Before Date : 15-OCT-2026
Delivery Note No. 1124102301
Destination : Argentina
Customer Ref. No : 4501701774
Customer Article No: 0420085301
Customer Name: DSM NUTRITIONAL PRODUCTS ARGENTINA S.A.
COLECTORA ESTE PANAMERICANA, RAMAL PILAR
C.U.I.T : 30-70782242-9

Article desc. CoA
Comment

CERTIFICATE OF ANALYSIS

DL-A-TOCOPHERYL ACETATE

Product Code:	0420085	Manufacturing Date:	16-Oct-2022
Analysis Number:	32485	Release Date:	14-Dec-2022
Lot Number:	UT22110348	Best Use Before:	15-Oct-2026

Test	Test Method	Result	Limits/Specification
Appearance:	Visual	clear viscous oil	clear viscous oil
Color:	Visual	slightly greenish-yellow	colorless, almost colorless, slightly yellow, slightly greenish-yellow
Identity (GC):	Gas chromatography	corresponds	corresponds
Optical rotation:	Polarimetry	0.01 °	-0.01 - +0.01 °
Heavy metals:	ICP-MS		
Heavy metals (total)		corresponds*	≤ 10 ppm
Lead		corresponds*	≤ 2 ppm
Arsenic		corresponds*	≤ 1 ppm
Mercury		corresponds*	≤ 0.1 ppm
Cadmium		corresponds*	≤ 0.5 ppm
Residual solvents:	Gas chromatography		
Pyridine		corresponds*	≤ 80 ppm
Toluene		corresponds*	≤ 80 ppm
Acidity:	Titration	<0.1 mL 0.10 N NaOH	≤ 1.0 mL 0.10 N NaOH
dl-α-Tocopheryl acetate and related substances:	Gas chromatography		
Impurity A		0.1 %	≤ 0.5 %
Impurity B		0.5 %	≤ 0.6 %
Impurity C (free Tocopherol)		0.10 %	≤ 0.5 %
Sum of impurities D + E		0.3 %	≤ 1.0 %
Any other impurity 1 (RRT:0.9502833333)		0.05 %	≤ 0.25 %
Any other impurity 2 (RRT:0.95715)		0.06 %	≤ 0.25 %

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Test	Test Method	Result	Limits/Specification
dl- α -Tocopheryl acetate and related substances:, cont.	Gas chromatography		
Any other impurity 3 (RRT:1.04531)		0.07 %	≤ 0.25 %
Any other impurity 4 (RRT:1.060755)		0.05 %	≤ 0.25 %
Any other impurity 5 (RRT:1.11515)		0.08 %	≤ 0.25 %
Any other impurity 6 (RRT:1.13261)		0.09 %	≤ 0.25 %
Any other impurity 7 (RRT:1.166295)		0.09 %	≤ 0.25 %
Total impurities		1.8 %	≤ 2.5 %
Assay (Ph.Eur.)		98.0 %	96.5 - 102.0 %
Assay (USP/FCC)		97.9 %	96.0 - 102.0 %

*) checked at regular intervals

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This lot has been analyzed against the substance specifications given above and released. The manufacturing and control records have been reviewed by our authorized Quality organization. The lot has been produced in conformity with applicable regulations and Good Manufacturing Practices for the uses stated in DSM Product Data sheet. A QA comment will be presented below if there is any deviation requiring restriction in the use of this lot.

Please consult your local representative or visit the DSM Customer Portal online for further compendial and compliance documentation.

QA Comment:

Not for use as an Pharmaceutical Ingredient API

Sandra Schoebel, Quality Assurance Manager

(This document has been generated and signed electronically)

DSM Nutritional Products Ltd
Quality Assurance

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CoA ID: 111994
Date of Issue: 14-Dec-2022