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Certificate of Analysis

Product Name:	α-Zearalenol solution ~10 µg/mL in acetonitrile, analytical standard
Product Number:	35406
Batch Number:	BCCP0113
CAS Number:	36455-72-8
Formula:	$C_{18}H_{24}O_5$
Formula Weight:	320.38
Storage Temperature:	-20 C
Expiration Date:	DEC 2026
Quality Release Date:	10 NOV 2025

TEST	SPECIFICATION	RESULT
CONCENTRATION COMP1	~ 10.0 UG/ML	10.1 UG/ML
MEASURING TOLERANCE P±	≤ 1.0 UG/ML	± 0.1 UG/ML
SOLVENT	ACETONITRILE	ACETONITRILE
PURITY (HPLC) COMP1	≥ 97.0 %	97.7 %
MEASURING TOLERANCE P± COMP1	≤ 1.0 %	0.6 %

Dr. Reinhold Schwenninger
Quality Assurance
Buchs, Switzerland

Alpha-Zearalenol solution, analytical standard 10 µg/mL in acetonitrile

1. General information

This document is designed and the certified value(s) and uncertainty(ies) are determined in accordance with ISO 33401:2024 [1] and Eurachem / CITAC Guides [2,3].

2. Description of the Reference Material (RM)

Name:	Alpha-Zearalenol solution, analytical standard 10 µg/mL in acetonitrile
Catalog number:	35406-1ML-BULK
Batch / Lot #:	BCCP0113
Date of production / Expiry date:	20.06.2023/ 18.12.2026
Starting material 1:	Alpha-Zearalenol, Lot # S08024A, Romer Labs Diagnostic GmbH
Physical description of RM:	Solution of alpha-Zearalenol in acetonitrile
Packaging of RM:	Amber glass ampoules fitted with teflon faced butyl septa and aluminium crimp cap, solution of 1 mL
Name and address of the supplier:	Sigma-Aldrich International GmbH c/o Sigma-Aldrich Production GmbH Industriestrasse 25 9470 Buchs Switzerland

2.1 Intended use of the RM

- for laboratory use only
- calibration of analytical instruments

2.2 Instruction for the correct use of the RM

The ampoules should be stored at approximately -18°C in a dark place. Before usage of the RM, the ampoules should be allowed to warm to room temperature. The recommended minimum sub-sample amount for all kinds of application is 1 mL. The expiry date of this RM is based on the current knowledge and holds only for proper storage conditions in the originally closed flasks/packages.

2.3 Hazardous situation

The normal laboratory safety precautions should be observed when working with this RM. Further details for the handling of this RM are available as safety data sheet (SDS).

Hazardous Ingredients	Concentration in %	Pictograms	Signal word	Hazard statement(s)
Acetonitrile	> 99.9		Danger	H225, H302, H312, H319, H332

3. Certified values and their uncertainties

Alpha-Zearalenol solution, analytical standard 10 µg/mL in acetonitrile		
Compound	**Mass concentration [a]**	
	Certified value [b]	Uncertainty [c]
Alpha-Zearalenol	10.1 µg/mL	± 0.1 µg/mL

[a] *Values are based on preparation data and confirmed experimentally by HPLC-UV*
[b] *Mass concentration based on weighed amount, purity and dilution steps*
[c] *Expanded uncertainty U (k = 2) of the value u_c according to GUM [4]*

3.1 Calculation of uncertainty

After the concentration of the gravimetric prepared solution was confirmed by HPLC-UV, the uncertainty of the calibrant solution was calculated on the basis of preparation [5].

Uncertainty components	Description	Standard uncertainty (u)
Minimum Purity (P) of solid alpha-Zearalenol (the uncertainty of the purity corresponds to the standard deviation of repeated measurements)	P = 97.7 %	**u (P) = 0.6 %**
Weighing procedure weighted sample: m_{ws}= 2.072 mg	U(m) = 0.0019 mg + 9.20 * 10^{-6} * m_{Toxin} u(m) = U(m)/2	**u (m) = 0.001 mg**
Dilution procedure steps	volumetric flask 1: V = 200 mL	**u (V) = 0.5 mL**

4. Discussion of traceability

This calibrant is certified on the basis of gravimetric preparation [5]. Thus the certified value (mass concentration of alpha-Zearalenol) is based on the weighed amount of the starting material 1 and is therefore traceable to the stated purity of the solid mycotoxin. High purity material represents a practical realization of concentration units, through conversion of mass to molar quantity.

5. Confirmation of certified value by HPLC-UV

The concentration value for alpha-Zearalenol of the gravimetric prepared solution was confirmed by HPLC-UV against an independently prepared reference batch.

column	Phenomenex Luna C18(2), 250 x 3mm, 5µm
injection volume	20 µL sample
solvent A	acetonitrile / water (50/50)
sample dilution	1:2 with water
flow rate	0.5 mL / min
DAD settings	238 nm

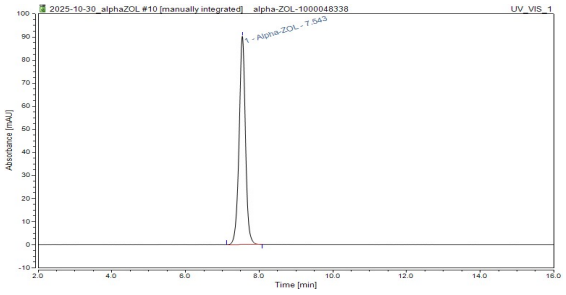

Figure 1: HPLC-UV separation of alpha-Zearalenol calibrant

	time [min]	area	concentration [a] [µg/mL]
alpha-Zearalanol	7.543	17.995	10.11 ± 0.30

[a] Mean of 6 replicate measurements against reference batch, confidence interval with P = 95 %

6. Further information

The purchaser must determine the suitability of this product for its particular use. Sigma-Aldrich International GmbH makes no warranty of any kind, express or implied, other than its products meet all quality control standards set by Sigma-Aldrich International GmbH. We do not guarantee that the product can be used for a special application.

This document has been computer generated and is valid without a signature.

References:

[1] ISO 33401:2024 - 1-10, "Reference materials – Contents of certificates, labels and accompanying documentation"

[2] Eurachem / CITAC Guide, 1-37, (2003), *"Traceability in Chemical Measurement"*

[3] Eurachem / CITAC Guide CG4, 1-133, (QUAM:2012.P1), *"Quantifying Uncertainty in Analytical Measurement", 3rd Ed.*

[4] International Organization for Standardization (ISO), (1995), *"Guide to the Expression of Uncertainty in Measurement"*, 1st Ed. Geneva, Switzerland

[5] R.D. Josephs, R. Krska, S. MacDonald, P. Wilson, H. Pettersson, J. AOAC Int. **86**, 50-60, (2003), *"Preparation of a Calibrant as Certified Reference Material for Determination of the Fusarium Mycotoxin Zearalenone"*