

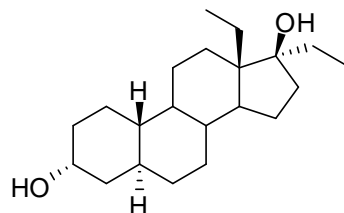


REFERENCE MATERIAL PRODUCT INFORMATION SHEET

Report ID: D820b.2018.01 (Ampouled 170209)

This batch of ampoules was prepared from the bulk material on 9th February 2017.

Compound Name: (\pm)-18a-Homo-17a-ethyl-5 α -estrane-3 α ,17 β -diol	Description: white powder
Collection Number: D820b	Batch Number: 16-S-09
Chemical Formula: C ₂₁ H ₃₆ O ₂	Molecular Weight: 320.5
CAS Registry Number: 24366-73-2	Release date: 3 rd February 2017
Structure:	



Relative stereochemistry

Synonyms: (\pm)-13 β , 17 α -Diethyl-5 α -gonane-3 α , 17 β -diol
(\pm)-(3 α ,5 α ,17 α)-13-Ethyl-18,19-dinorpregnane-3,17-diol

The compound is supplied as a dried aliquot in a sealed ampoule and is intended for a single use to prepare a standard solution containing D820b. Open the ampoule and carefully rinse the interior at least three times with a suitable organic solvent (e.g. chloroform). This will transfer 977 \pm 20 μ g of anhydrous 18a-Homo-17a-ethyl-5 α -estrane-3 α ,17 β -diol. The uncertainty is stated at the 95% coverage interval.

Warning: This material is sensitive to the quality of the silanised glass liner when injected at elevated temperature (~ 250 °C) into a GC instrument.

GC-FID: Instrument: Agilent 7890
Column: HP-1, 30 m \times 0.32 mm I.D. \times 0.25 μ m
Program: 180 °C (1 min), 15 °C/min to 250 °C, 30 °C/min to 280 °C (5 min)
Injector: 250 °C Detector Temp: 320 °C
Carrier: Helium Split ratio: 20/1
Relative peak area response of main component :
Initial analysis: Mean = 97.7%, s = 0.01% (7 ampoules in duplicate, March 2017)
Re-analysis: Mean = 97.6%, s = 0.1% (5 ampoules in duplicate; April 2018)

Expiration of certification

The property values are valid till 11th April 2021, i.e. three years from the date of re-certification provided the **unopened** material is handled and stored in accordance with the recommendations below. The material as issued in the unopened container and stored as recommended below should be suitable for use beyond this date, subject to confirmation of batch stability from the issuing body.

The expiry date/shelf life does not apply to ampoules that have been opened. In such cases it is recommended that the end-user conduct their own in-house stability trials.

The long-term stability of the compound in solution has not been examined.

In the absence of stability data the measurement uncertainty at the 95% coverage interval has been expanded to accommodate any potential change in the property value. The stability component has been estimated from stability trials conducted on similar materials by NMI Australia over the last 10 years.

Homogeneity assessment

The homogeneity of the material was assessed using purity assay by GC-FID on seven randomly selected ampoules of the material. The material was judged to be sufficiently homogeneous at this level of sampling as the variation in analysis results between samples was not significantly different at a 95% confidence level from that observed on repeat analysis of the same sample.

Recommended storage

When not in use, this material should be stored at or below 4 °C in a closed container in a dry, dark area.

Intended use

For *in vitro* laboratory analysis only.

Caution

Treat as hazardous substance. Use appropriate work practices when handling to avoid skin or eye contact, ingestion or inhalation of dust.

Legal notice

Neither NMI nor any person acting on NMI's behalf assumes any liability with respect to the use of, or for damages resulting from the use of, this reference material or the information contained in this certificate.

Authorised by:

S. R. Davies

Dr Stephen R Davies
Team Leader,
Chemical Reference Materials, NMI
Dated: 20 April, 2018.

Characterisation data and property values specified in this report supersede those in all reports issued prior to 20th April 2018.