



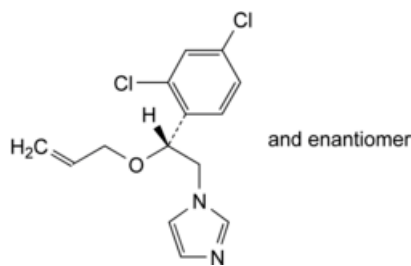
Edition: BP 2025 (Ph. Eur. 11.6 update)

Enilconazole



General Notices

(Enilconazole for Veterinary Use, Ph. Eur. monograph 1720)



C₁₄H₁₄Cl₂N₂O 297.2 35554-44-0

Action and use

Antifungal.

Ph Eur

DEFINITION

1-[(2*RS*)-2-(2,4-Dichlorophenyl)-2-(prop-2-enyloxy)ethyl]-1*H*-imidazole.

Content

98.5 per cent to 101.5 per cent (dried substance).

CHARACTERS

Appearance

Clear, yellowish, oily liquid or solid mass.

Solubility

Very slightly soluble in water, freely soluble in ethanol (96 per cent), in methanol and in toluene.

IDENTIFICATION

Infrared absorption spectrophotometry ([2.2.24](#)).

TESTS

Optical rotation ([2.2.7](#))

-0.10° to + 0.10°.

Dissolve 0.1 g in [methanol R](#) and dilute to 10 mL with the same solvent.

Related substances

Gas chromatography ([2.2.28](#)). *Prepare the solutions immediately before use and protect from light.*

Test solution Dissolve 0.100 g of the substance to be examined in [toluene R](#) and dilute to 100.0 mL with the same solvent.

Reference solution (a) Dissolve 10 mg of [enilconazole CRS](#) and 10 mg of [enilconazole impurity E CRS](#) in [toluene R](#) and dilute to 100 mL with the same solvent.

Reference solution (b) Dilute 5.0 mL of the test solution to 100.0 mL with [toluene R](#). Dilute 1.0 mL of this solution to 10.0 mL with [toluene R](#).

Column:

- *material:* fused silica;
- *size:* *l* = 25 m, Ø = 0.32 mm;
- *stationary phase:* [phenyl\(5\)methyl\(95\)polysiloxane R](#) (film thickness 0.52 µm).

Carrier gas [helium for chromatography R](#).

Flow rate 1.3 mL/min.

Split ratio 1:38.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 6.4	100 → 260
	6.4 - 14	260
Injection port		250
Detector		300

Detection Flame ionisation.

Injection 2 µL.

Identification of impurities Use the chromatogram obtained with reference solution (a) to identify the peak due to impurity E.

Relative retention With reference to enilconazole (retention time = about 10 min): impurity A = about 0.6; impurity B = about 0.7; impurity C = about 0.8; impurity D = about 0.9; impurity E = about 1.03; impurity F = about 1.1.

System suitability Reference solution (a):

- [resolution](#): minimum 2.5 between the peaks due to enilconazole and impurity E.

Limits:

- *impurities A, B, C, D, E, F:* for each impurity, not more than twice the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent), and not more than 1 such peak has an area greater

than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent);

— *unspecified impurities*: for each impurity, not more than 0.4 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.20 per cent);

— *total*: not more than 4 times the area of the principal peak in the chromatogram obtained with reference solution (b) (2.0 per cent);

— *disregard limit*: 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Loss on drying (2.2.32)

Maximum 0.5 per cent, determined on 1.000 g by drying *in vacuo* at 40 °C for 4 h.

Sulfated ash (2.4.14)

Maximum 0.1 per cent, determined on 1.0 g.

ASSAY

Dissolve 0.230 g in 50 mL of a mixture of 1 volume of [anhydrous acetic acid R](#) and 7 volumes of [methyl ethyl ketone R](#). Titrate with [0.1 M perchloric acid](#) using 0.2 mL of [naphtholbenzein solution R](#) as indicator.

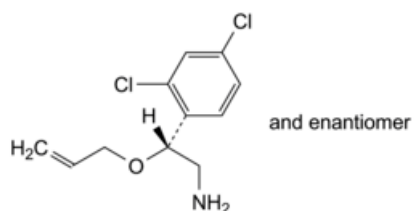
1 mL of [0.1 M perchloric acid](#) is equivalent to 29.72 mg of $C_{14}H_{14}Cl_2N_2O$.

STORAGE

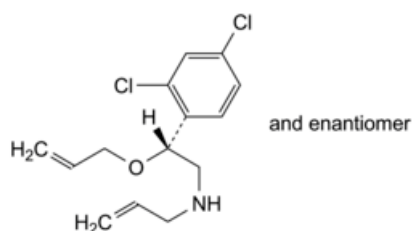
In an airtight container, protected from light.

IMPURITIES

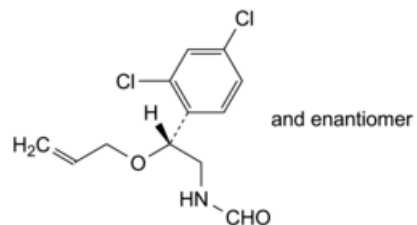
Specified impurities A, B, C, D, E, F.



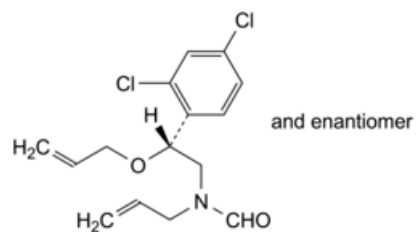
A. (2RS)-2-(2,4-dichlorophenyl)-2-(prop-2-enyloxy)ethanamine,



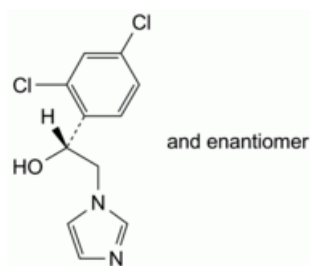
B. N-[(2RS)-2-(2,4-dichlorophenyl)-2-(prop-2-enyloxy)ethyl]prop-2-en-1-amine,



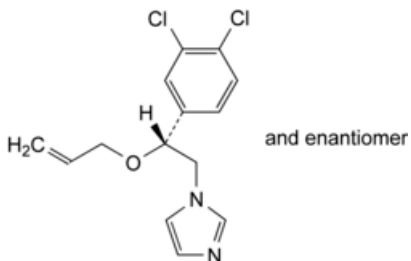
C. *N*-[(*2RS*)-2-(2,4-dichlorophenyl)-2-(prop-2-enyloxy)ethyl]formamide,



D. *N*-[(*2RS*)-2-(2,4-dichlorophenyl)-2-(prop-2-enyloxy)ethyl]-*N*-(prop-2-enyl)formamide,



E. (*1RS*)-1-(2,4-dichlorophenyl)-2-(1*H*-imidazol-1-yl)ethanol,



F. 1-[(*2RS*)-2-(3,4-dichlorophenyl)-2-(prop-2-enyloxy)ethyl]-1*H*-imidazole.