# TECHNICAL DATA SHEET



Trade name : PIPERONYL BUTOXIDE PHARMA GRADE GMP

THE PRODUCT COMPLIES WITH PIPERONYL BUTOXIDE BRITISH PHARMACOPOEIA (VET) MONOGRAPH AND THE GLOBAL GMP STANDARDS FOR ACTIVE PHARMACEUTICAL INGREDIENTS (ICH Q7A)

### CHEMICAL IDENTIFICATION

Definition Not less than 94.0 % of C<sub>19</sub>H<sub>30</sub>O<sub>5</sub>

Nomenclature

Common name : Piperonyl Butoxide

**IUPAC** name : 5-{[2-(2-butoxyethoxy)ethoxy]methyl}-6-propyl-1,3-benzodioxole CA name : 1,3-Benzodioxole, 5-[[2-(2-butoxyethoxy)ethoxy]methyl]-6-propyl-

CAS number : 51-03-6

EC number : 200-076-7

Molecular formula : C<sub>19</sub>H<sub>30</sub>O<sub>5</sub>

Molecular weight 338.40

Structural formula

#### PRODUCT SPECIFICATIONS

Chemical assay (ENDQC-710 method by HRGC)

Piperonyl Butoxide ≥ 94.0 % w/w

Butyl Carbitol® ≤ 1.50 % a/a

Dipiperonyl methane (DPM) ≤ 2.00 % a/a

Dipiperonyl ether (DPE) ≤ 1.50 % a/a

Dihydrosafrole (DHS) ≤ 50 mg/kg

Any other secondary peak (each) ≤ 0.50 % a/a

Any other secondary peaks (total) with an area ≤ 2.50 % a/a

≥ 0.1 %, other than Butol, DPM, DPE, DHS

Chloromethyl DHS ≤ 80 mg/kg N,N-Dimethyformamide (DMF) (ENDQC-102 ≤ 880 mg/kg

method)

Dichloromethane (DCM) (ENDQC-102 method) : ≤ 600 mg / Kg

NOTE: Endura reserves the right to make amendments to the data reported in this sheet either in compliance to any official body's updating or in agreement with Internal Company decisions.

The reported information is, to the best of our knowledge, as accurate and complete as possible and is given in good faith but without warranty from our part. Any use for Registration purposes must be authorised by Endura in advance.

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Trade name : PIPERONYL BUTOXIDE PHARMA GRADE GMP

### PRODUCT SPECIFICATIONS (continues)

Acidity number (ENDQC-6 method) :  $\leq 0.10 \text{ mg KOH/g}$ 

**Density** (ENDQC-4 method) : 1.050-1.065 g/cm<sup>3</sup> at 20°C

**Colour** (ENDQC-7 method) : ≤ 2.5 (Gardner scale)

Appearance (visual method) : Clear oily liquid, colourless to light yellow

**Refractive index** (Ph. Eur. 2.2.6.)\* :  $1.494-1.504 \text{ n}^{20}_{\text{D}}$ 

**Sulphated ash** (Ph. Eur. 2.4.14)\*\* :  $\leq 0.2 \% \text{ w/w}$ 

Microbial Counts (Ph. Eur. 2.6.12)

TAMC  $\leq$  100 CFU/1g TYMC  $\leq$  100 CFU/1g

#### ADDITIONAL INFORMATION

Odour : Slightly aromatic

**Boiling point** : 203 °C at 278 Pa

Vapour pressure : 2.11 x 10<sup>-7</sup> hPa at 60°C

Flash point : 179.2 °C

**Solubility** : Soluble in all common organic solvents (n-hexane, toluene,

1,2-dichloroethane, 2-propanol, acetone, ethyl acetate),

including mineral oils.

Partition coefficient

(Log Pow)
Identification

: 4.8

UV-vis spectra (220-350 : Well defined maxima at 238 nm and 290 nm.

nm)

IR spectra Concordant with the reference spectrum of Piperonyl

Butoxide.

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PBO Pharma Grade GMP Rev.8 October 2021

<sup>\*</sup> Equivalent to the BP Vet Method reported in Appendix V E.

<sup>\*\*</sup> Equivalent to the BP Vet Method reported in Appendix IX A, Method II.