Specification

1.01806.0000 Benzyl benzoate EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP

	Specification	
Assay (by alcalimetric following saponification)	99.0 - 100.5	%
Assay (HPLC, calc. on anhydrous substance)	98.0 - 102.0	%
Identity (IR-spectrum)	conforms	
Identity (HPLC)	conforms	
Identity (wet chemistry)	conforms	
Identity (UV/VIS)	conforms	
Acidity (Ph Eur)	conforms	
Acidity (ChP, USP)	conforms	
Acidity (JP)	conforms	
Refractive index (n 20/D)	1.568 - 1.570	
Density (Ph Eur, d 20/20)	1.118 - 1.122	
Density (ChP, USP, d 25/25)	1.116 - 1.120	
Solidification point	≥ 18.0	°C
Chloride (Cl)	≤ 350	ppm
Benzaldehyde	≤ 0.05	%
Benzene (HS-GC)	≤ 2	ppm
Methanol (HS-GC)	≤ 3000	ppm
Toluene (HS-GC)	≤ 890	ppm
Related substances (HPLC) (Benzaldehyde)	≤ 0.05	%
Related substances (HPLC) (Major unspecified impurity)	≤ 0.1	%
Related substances (HPLC) (Sum of all unspecified impurities)	≤ 1.0	%
Other residual solvents (ICH Q3C)	excluded by production process	
Sulfated ash	≤ 0.05	%
Water (according to Karl Fischer)	≤ 0.3	%
Total aerobic microbial count (TAMC)	≤ 10^2	CFU/ml
Total combined yeasts/moulds count (TYMC)	≤ 10^1	CFU/ml
Endotoxins	≤ 10	I.U./ml

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).

Corresponds to Ph Eur, BP, ChP, JP, USP.

The original manufacturer name and address will be disclosed subsequent to signing a confidentiality agreement.

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Dr. Sebastian Lips
Responsible laboratory manager quality control

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