

Specification

1.02975.0000 Sorbitol FP liquid (sorbitol syrup, noncrystallizing) EMPROVE® ESSENTIAL Ph Eur,BP,NF,E 420

	Specification		
olid matter	69.0 - 72.0	%	
orbitol (HPLC, calc.on anhydrous substance)	72.0 - 92.0	%	
orbitol (HPLC)	≥ 50.0	%	
entity	passes test		
H-value (14 %; water)	5.0 - 7.5		
ppearance of solution (14 %; water)	passes test		
onductivity (25°C)	≤ 10	μS/cm	
s (Arsenic)	≤ 1	ppm	
i (Nickel) (calc. on anhydrous substance) (*)	≤ 1	ppm	
b (Lead)	≤ 0.5	ppm	
thylene glycol (HPLC)	≤ 0.10	%	
iethylene glycol (HPLC)	≤ 0.10	%	
annitol (HPLC)	≤ 6.5	%	
educing sugars after hydrolysis/total sugar s glucose)	≤ 9.3	%	
educing sugars (as glucose)	≤ 0.2	%	
ulfated ash (calc.on anhydrous substance)	≤ 0.1	%	
/ater	28.5 - 31.0	%	
esidual solvents (ICH Q3C)	excluded by manufacturing process		
icrobiological test	passes test		
olony count (aerobic bacteria (TAMC))	≤ 10³	CFU/ml	
olony count (Yeasts and moulds (TYMC))	≤ 10²	CFU/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, NF, E 420

Conforms to the purity criteria on food additives according to the current European Commission Regulation.

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

Christin Leistner

Responsible laboratory manager quality control

This document has been produced electronically and is valid without a signature.