



Specification

8.17081.0000 Sodium caprylate EMPROVE® EXPERT Ph Eur,ChP,NF

Specification

Appearance (description)	finely crystalline powder	
Appearance (color)	white or almost white	
Assay (perchloric acid titration, calc. on anhydrous substance)	99.0 - 101.0	%
Identity	passes test	
Identity (GC, Retentiontime)	conforms	
Appearance of solution (Ph Eur)	clear and colorless	
Appearance of solution (ChP)	clear and colorless	
Appearance of solution (NF)	clear and colorless	
pH-value (10 %; water)	8.0 - 10.5	
Al (Aluminium)	≤ 50	ppm
Heavy metals (as Pb) (ChP)	≤ 0.0005	%
Related substances (GC) (largest single impurity)	≤ 0.3	%
Related substances (GC) (Sum of all impurities)	≤ 0.5	%
Residual solvents (ICH Q3C)	excluded by production process	
Water (according to Karl Fischer)	≤ 3.0	%
Endotoxins	< 20	I.U./g
Total aerobic microbial count (TAMC)	≤ 10 ²	CFU/g
Total combined yeasts/moulds count (TYMC)	≤ 10 ¹	CFU/g

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 Ph Eur, ChP, NF

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

Dr. Timo Huxel

Responsible laboratory manager quality control

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