

Specification

1.06345.0000 Sodium dihydrogen phosphate dihydrate EMPROVE® ESSENTIAL Ph Eur, BP,ChP,USP,JPE,E 339

	Spec. Values	
Assay (alkalimetric, calculated on dried substance)	98.0 - 100.5	%
Assay (alkalimetric; dried substance)	98.0 - 101.0	%
Assay (alkalimetric, calculated on dried substance; ChP)	98.0 - 100.5	%
Assay (alkalimetric, calculated on anhydrous substance)	98.0 - 100.5	%
Identity	passes test	
Appearance of solution	passes test	
In water insoluble matter (calculated on dried substance)	≤ 0.15	%
pH-value (1 %, water)	4.1 - 4.7	
pH-value (5 %; water)	4.2 - 4.5	
pH-value (5.7 %; water)	4.1 - 4.5	
Acidity	4.1 - 4.7	
Chloride (CI)	≤ 0.005	%
Fluoride (F)	≤ 0.001	%
Sulfate (SO ₄)	≤ 0.01	%
Heavy metals (as Pb)	≤ 0.0005	%
Al, Ca and other elements detectable with ammonia	passes test	
Al (Aluminium)	≤ 0.01	%
As (Arsenic)	≤ 0.0001	%
Calcium salt	≤ 0.01	%
Cd (Cadmium)	≤ 0.0001	%
Fe (Iron)	≤ 0.001	%
Hg (Mercury)	≤ 0.0001	%
Pb (Lead)	≤ 0.0001	%
Substances reducing potassium permanganate (as O)	passes test	
Residual solvents (ICH Q3C)	excluded by production process	
Loss on drying (130 °C)	22.0 - 24.0	%
Water (according to Karl Fischer)	22.0 - 24.0	%

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, USP, JPE, E 339

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

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Kristin Starke

Responsible laboratory manager quality control

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