



Specification

Concerning Product:	
Article number	13472350BEU
Trade name / designation / denomination	Monosodium phosphat 2-hydrat, EP/USP
CAS number	13472-35-0
Other names / synonyms	•Phosphoric acid, sodium salt, hydrate (1:1:2); •Sodium Phosphate, Monobasic, Dihydrate; •Sodium dihydrogen phosphate dihydrate; •Sodium phosphate monobasic dihydrate; •sodium dihydrogen phosphate dihydrate;
EC number	231-449-2
Molecular weight [g / mol]	156.008
Formula	NaH ₂ PO ₄ +2H ₂ O

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance of solution		passes test	
Appearance		colorless crystals	
Physical parameter			
Water content		18 – 26,5	%
Loss on drying		(130 °C / 4h) 21,5 – 24	%
pH value		5%: 4,2 – 4,5	
Reducing substances		passes Test	
Identity			
Assay	Ph.EUR	on dried basis 98 – 100,5	%
Assay	USP	on dried basis 98 – 103,0	%
Identification		passes test	
Impurities			
Sulphates (SO ₄)		≤ 300	ppm
Impurity		Al, Ca and related elements: passes Test	%
Impurity		H ₂ O-insoluble substances ≤ 0,2	%
Elemental Impurities			
Arsenic (As)		≤ 1	ppm
Cadmium (Cd)		≤ 0,5	ppm
Chlorides (Cl)		≤ 140	ppm
Cobalt (Co)		≤ 5	ppm
Iron (Fe)		≤ 10	ppm
Mercury (Hg)		≤ 1	ppm

Nickel (Ni)		≤ 6	ppm
Lead (Pb)		≤ 0,5	ppm
Vanadium (V)		≤ 3	ppm

Supplemental information:

Shelf life: 2 years

Note: Country of Origin: Germany

Following ICH Q3D guideline on elemental impurities and the risk assessment for oral route of administration the manufacturer confirms, that class 2B or class 3 elements are not intentionally added during the manufacture of above mentioned product.

The aqueous solution of Monosodium Phosphate has an acid action. Monosodium Phosphate melts on heating to give Polyphosphates of varying chain lengths. Monosodium Phosphate has good buffering properties in the acid range. Due to its physical properties and the content of water of hydration, Monosodium Phosphate tends to form lumps. This tendency generally increases over time of storage, especially when the material is exposed to high temperature, high humidity levels or high pressure. These lump formations

The manufacturer confirms that none of the solvents listed in the supplement 467 "Residual solvents" of the United States Pharmacopeia and chapter 5.4 of the European Pharmacopeia are used in the manufacture of above mentioned product. He confirms that above mentioned product complies with the ICH Q3C guideline for residual solvents

Storage conditions: Store at room temperature in protected areas and in well closed containers. As storage conditions, we recommend peak temperatures being below 30°C and the relative humidity being constantly below 65%

Usage: For excipient use

Chemische Werke Hommel GmbH & Co.KG

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Waltrup, 18. Dec. 2023

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