

Certificate of Analysis

Date

03.06.2020

Purchase order/date

75361643 / 19.05.2020

Delivery item/date

7165689 000010 / 03.06.2020

Order item/date

3395895 000070 / 19.05.2020

Contact:

CSC: Ms. Costa, Tel. + , Mail: customerservice@budenheim.com

N 52-71

Disodium phosphate 2-hydrate

Ph.Eur., USP

Complies to chemical specification currently required in EU regulation 231/2012 for E 339(ii).

Material-No. 0000002263	Batch-No.: C94660A	Production date: (D.M.Y) 23.03.2020	Best before: (D.M.Y) 23.03.2023	Delivered quantity: 300,00 KG
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Characteristic	Unit	Value	Lower Limit	Upper Limit	Method
Assay	%	100,1	98,0	100,5	P11
P2O5	%	40,0	39,1	40,1	P11
Na2O	%	34,9	34,1	35,0	P11
Loss on ignition (800 °C)	%		25,1	25,5	GV1
Loss on drying (105 °C, 4h)	%	19,9	18,5	21,0	TV1
Loss on Drying (130°C, 4h)	%	20,1	19,5	21,0	TV1
pH (1%)		9,3	9,0	9,6	PH-POT
Iron	ppm			5	OES
Cadmium	ppm			0,5	ICP-MS
Lead	ppm			0,5	ICP-MS
Arsenic	ppm			1	ICP-MS
Mercury	ppm			1	ICP-MS
Cobalt	ppm			5	OES
Vanadium	ppm			3	ICP-MS
Nickel	ppm			6	OES
Chloride	ppm			10	CLPHOT
Fluoride	ppm			10	F10
Sulfate	ppm			50	SO10
Identification (Tests)				passes Test	ID10
Reducing substances				passes Test	RS10
Solubility 10%				passes Test	VIS
H2O-insoluble substances	%	< 0,005		0,005	UR10

Monosodium Phosphate	%	0,7	2,5	PHEUR
Solution appearance			passes Test	VIS10
pyro-P2O5 calc. on Na4P2O7	%	0,1	2,0	HPIC1

Country of Origin: Germany

The results of analysis were obtained using the methods listed above. If results are not listed, the conformity to specification is assured by periodical testing.

We confirm 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. We confirm that above mentioned product complies with the ICH Q3C guideline for residual solvents.

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

Any information contained herein is made to the best of our ability on the basis of current industrial practice and our own knowledge and experience. Any responsibility for damages resulting from the use of or reliance upon such information or products such information refers to is limited pursuant to our Conditions of Sale and Supply. The information contained herein shall not cause the purchaser or any other person or entity using or intending to use our products to refrain from testing our products and/or reviewing (and, if relevant, respecting) any conflicting patent and other proprietary rights; and we expressly request and invite the customer or such other user of our products to perform such tests, have such tests performed prior to any commercial use or other application of our products for the specific use and application intended and to review (and, if relevant, to respect) any conflicting patent and other proprietary rights relevant for the specific product and/or use.

The data shown in this document are provided for information only, and does not relieve receiver from performing any mandatory inspections or testing upon delivery.

This certificate of analysis is computer generated, thus no signature is required.

Budenheim, 03.06.2020

Manager Quality Control Dr. André Lemke